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Selecting a New Analyzer for the Hematology Laboratory: The Experience at OhioHealth Hospitals

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ABSTRACT

This paper details a decision-making process used by OhioHealth Hospitals to select a company to supply all hematology laboratories in the system with instruments, reagents, and service. The 2-phase approach included an initial assessment of 5 companies. In the second phase, 2 companies, Beckman Coulter and Sysmex, were evaluated by an in-depth assessment of product line, technical performance, operational performance, and financial analysis. Results from all surveys and side-by-side studies are presented. The task force made up of representatives from all hospital laboratories made a final recommendation to partner with Beckman Coulter. *Lab. Hematol.* **2001;7:245–254**

KEY WORDS: **Participative management · Decision-making process · Task force · Instrument evaluation · Hematology analyzer · Coulter Gen•S · Coulter HmX · Coulter AcT diff · Sysmex SE9500 · Sysmex SF3000 · Sysmex KX-21**

INTRODUCTION

OhioHealth Hospitals of Central Ohio is a group of 4 hospitals located on different sites in Columbus, Ohio. The hospital group is composed of Riverside Hospital, Grant Medical Center, Doctors North, and Doctors West. The hospital specialties include cardiac surgery, oncology, maternity, orthopedics, and a level I trauma center. Grant and Riverside have a combined testing volume of 4.58 million per year, whereas Doctors North test volume is 1.62 million per year and Doctors West is 700,000 per year. Grant and Doctors West are community hospitals that perform routine laboratory testing. Doctors North is also a community hospital that performs routine testing as well as some special chemistry testing. Riverside is a tertiary care facility that is a full-service laboratory, performing routine testing, special chemistry, and the special hematology and special coagulation testing for the OhioHealth Hospital System. In addition to our in-patient specialties, we have an extensive outreach program that includes 600 clients within a 75-mile radius.

Currently the laboratories at the various hospitals use hematology systems from different companies. This situation results in significant redundancy in service and reagent sources and contracts. Patient results also might be compromised by differences in technology and quality. When new hematology instrumentation was needed for the laboratories in the OhioHealth Hospitals group, we decided to select a single company to provide hematology analyzers, reagents, and service throughout the hospital system. We formed a task force to investigate the potential hematology vendors. Representatives were selected from the 4 hospitals, and the Riverside Core Lab Manager facilitated the group. This investigation used participative management techniques, whereby the group set the criteria and designed the process we would use to make a final selection

A 2-phase approach to this investigation was taken. We felt it was important to select a supplier that could provide products and service to the entire hospital system, not just the high-volume laboratory. We wanted appropriate instrumentation for each laboratory, regardless of its size, with consistency in technology and quality of results. The initial

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phase of the evaluation included gathering information and assessing each of the 5 hematology companies based on predetermined criteria developed by the team. The initial phase concluded with the selection of the final 2 companies that we would further evaluate in the second phase.

The 5 instrument companies that were included in the initial phase of the evaluation were Abbott Diagnostics (Mountain View, CA), ABX (Montpelier, France), Bayer Diagnostics (Tarrytown, NY), Beckman Coulter (Fullerton, CA), and Sysmex Corporation (Chicago, IL). The task force gathered information from multiple sources that included site visits to various laboratories, attendance at national meetings, and in-services from company representatives. The information was compiled and evaluated by the task force according to our preset criteria. A comprehensive set of 45 criteria was evaluated for each company's small, midsized, and fully automated instrument systems. A synopsis of this data is shown in Table 1.

Based on this initial assessment, 2 companies were recommended by the task force for further consideration through side-by-side instrument evaluations. The hospital directors reviewed and agreed with the recommendation of the task force. The companies selected to participate in the side-by-side laboratory evaluation were Beckman Coulter and Sysmex. Each of these companies was judged to have the right mix of products and services to meet the needs of all laboratories in the OhioHealth group.

The side-by-side phase 2 evaluations were conducted at each of 3 hospitals. Each laboratory focused on the instruments from the 2 manufacturers that best fit their requirements. The evaluation process was the same at each site. Differences in the number of samples analyzed reflected differences in the sample populations and workflow at each site. Representative data from all systems at all sites are presented in this paper. The final choice of company is highly dependent on the performance, ease of use, and reliability of all systems.

MATERIALS AND METHODS

Instrumentation

Instrument evaluations were conducted at 3 laboratory sites in the OhioHealth group. The systems evaluated and the site at which they were evaluated were:

Riverside Hospital:	Coulter Gen•S, Sysmex SE9500
Grant Medical Center:	Coulter HmX, Sysmex SF3000
Doctors North:	Coulter AcT diff, Sysmex KX-21

Riverside Hospital, which has the largest daily volume of complete blood counts (CBCs) in the system, evaluated the Coulter Gen•S and Sysmex SE9500. These are the high-volume fully automated hematology systems with cutting-edge technology from their respective manufacturers. At Grant Medical Center, we evaluated the Coulter HmX and the Sysmex SF3000. These systems were designed for the midvolume laboratory and feature automated sampling with cap-pierce capability. They also include a 5-part white blood cell (WBC) differential and reticulocyte analysis. The AcT diff and KX-21 are systems well suited for the low-volume laboratory. Both analyzers have cap piercing and a 3-part differential.

Reagents used on all systems were those recommended and provided by the manufacturers. All systems were calibrated and controlled according to the manufacturers' recommendations. The manufacturers also provided calibration and control materials.

Service representatives from each company set up the hematology instruments. The manufacturers provided training for the technologists designated to perform the instrument evaluations. These technologists at each site operated the instrument systems and analyzed all samples throughout the evaluation. During the actual evaluation period, no representatives from the participating companies were present in the laboratory. After all study data had been collected, other technologists in the laboratories had the opportunity to review and operate the evaluation instruments. These technologists received in-services and training from the manufacturers and were given time to run samples on each analyzer for several weeks. At the conclusion of the evaluation period, these technologists also completed surveys for each analyzer they used.

Evaluation Methods

Performance of each set of analyzers was evaluated based on precision, carryover, sample stability, comparison of results with those from current methods, and false-positive/negative rates. Once collected, all data were analyzed by both the instrument representatives and members of the task force.

Precision. The objective of the precision study was to verify that performance was within manufacturers' stated limits for each mode of operation. Within-run precision was determined for each of the instruments. The same sample from a hematologically normal donor was used for each run on the same instrument. Different samples were used for the different instruments. For the instruments with an automated mode, aliquots of the sample were made into 10 (plain red-topped) tubes. In the automated mode, the 10 tubes were placed onto the instrument rack and each was analyzed. For the high- and midvolume systems with both automated and manual modes, precision was also evaluated in the manual mode. In the manual mode, precision was measured by analyzing 10 consecutive replicates of the sample, mixing by inversion between aspirations. The mean, SD, and coefficient of variation (CV) were calculated for each parameter, each mode, and each instrument.

Run-to-run precision was evaluated to provide documentation of the calibration stability of all parameters. Results were determined by analyzing appropriate control materials on a daily basis for a minimum of 10 days. Three levels of control material, specified by the manufacturer, were used for each analyzer daily. The mean, SD, and CV were analyzed for each sample set.

TABLE 1. Initial Phase Survey

Issue	Abbott CD1700, CD3200, CD4000	ABX Micros 60, Pentra 60, Pentra120 retic	Bayer Advia 60, Advia120 basic, Advia 120	Beckman Coulter AcTdiff2, HmX, Gen•S	Sysmex KX21, SF3000, SE9500
Maintenance/service/reliability					
Routine maintenance	10 min/d	None daily	7 min/d	None daily	~20 min/d
Maintenance by modem	No	No	Yes	Gen•S only	No
Online help	Yes, all systems	Pentra 120 & 60	Yes	Gen•S only/CD-ROM	No
Service	Yes, local	Yes, local		3 experienced representatives in city	3 experienced representatives within 3 h of city
Downtime	Not evaluated	Not evaluated	Not evaluated	Very dependable; have decreased service contract level for $ savings	More than desired; has improved
Sample handling					SE9500 has problems with tubes thrown out of holder onto the floor or into the analyzer
System characteristics					
Ability to handle high volume of samples	110/h CBC; 75/h differential; 60-70/h all other	Pentra120, 130/h; others, 60/h	Advia120, 120/h; Advia60, 60/h	Proven ability to handle very high volumes	Some concerns
Depth of product line	Several systems available	Several systems available	3 configurations, 1 with autosampler	Very good	Very good
Calibration	Calibrate every other mo			Done by technologist as needed, but at least every 6 mo	Done by service every 6 mo
Technology	Different technology on different systems	Same technology	Same technology	Less advanced	Advanced
Ease of use				Very easy to use	Not so easy to use analyzer
Reagents					
Same across product line	No	No	Yes	Yes	Yes
Number of reagents	CD4000, 5; CD3200, 4	Pentra120 with retics, 6; Pentra 60, 5; Micros 60, 3	10	All systems, 4	SE9500, 9; SF3000, 4
Software					
Rules-based technology	No			Gen•S only, CD-ROM	No
Online training	No			Gen•S only	No
Usability				More complex	Easy
Autovalidation				Need to do through laboratory information system	Need to do through laboratory information system
Printing					
Downtime procedure				Gen•S can print multiple copies	Can print only 1 patient copy
Flag printing				Can select which flags you want to use to generate a print copy	Options: print all or print none
Other considerations					
Nucleated red blood cell enumeration	Yes, CD3200				
Automation	No		No		
Slide-making/staining	Yes, CD3200 & CD4000	Yes, Pentra120	Yes, Advia120		

Carryover. Carryover was determined for each instrument system by analyzing 2 normal patient specimens followed by 3 replicates of diluent. Percentage carryover was calculated as follows for each of the directly measured CBC parameters on each system:

$$\% \text{ carryover} = \{(\text{diluent } 3 - \text{diluent } 1)/\text{sample } 2\} \times 100$$

Sample Stability. Sample stability studies were conducted on each of the systems under evaluation. Six routine samples were selected for the study and analyzed within 1 hour of phlebotomy (time 0). Three samples were stored at room temperature and 3 were stored refrigerated. Different samples with similar characteristics were used on each of the analyzers. Samples were subsequently analyzed at 1, 4, 8, 12, 24, 48, and 56 hours. Manual differentials were performed on each sample at 0 and 56 hours. For each parameter, the difference in result between each analysis and time 0 (time 8 – time 0; time 12 – time 0, etc) was calculated. Parameters were considered stable if the differences between them did not exceed twice the manufacturer's specification for precision.

Method Comparison and Flagging Efficiency. For each set of analyzers being compared, a different set of patient specimens was used to determine accuracy. The number of samples analyzed at each site varied according to the workflow as follows:

Riverside Hospital:	Gen•S/SE9500	250 samples
Grant Medical Center:	HmX/SF3000	200 samples
Doctors North:	AcT diff/KX-21	100 samples

At all sites, samples were analyzed on both test systems within 2 hours after being analyzed on that hospital's primary analyzer. This procedure minimized any differences due to time factors. The CBC parameters were compared between results from each of the test instruments and the primary routine analyzer. Differential parameters were compared with both the primary instrument result and a 200-cell manual differential (100-cell manual differential on each of 2 slides read by 2 technologists for a total 200-cell differential).

Efficiency of the flagging system for each of the analyzers under investigation was determined by comparing those samples that were flagged as abnormal to the result from the manual WBC differential. The manual WBC differential was used as the reference, and the routine laboratory criteria were used to judge if a specimen was normal or abnormal. The routine laboratory criteria for judging a specimen abnormal are the following:

- >5 metamyelocytes
- ≥1 myelocyte, promyelocyte, or blast
- >8 atypical lymphocytes
- >3 nucleated red blood cells
- clumped platelets
- >2+ poikilocytosis

The true/false-positive and true/false-negative rates and efficiency of each system, including the current hematology systems, were determined.

Technologists' Assessment

At the conclusion of the laboratory evaluation, each evaluator completed a survey. This helped the task force determine how each analyzer met the needs of the individual laboratory and focused on important operational issues such as ease of operation, data terminal navigation, quality-control package, instrument maintenance, sample throughput, and minimal operator intervention. The staff technologists also filled out a similar evaluation form that stressed these same issues.

RESULTS

System Evaluation

Precision. Within-run precision results are shown in Table 2 for each of the analyzers under evaluation. Results for the closed-vial/automated sampling mode are shown for all systems. For the high- and midvolume systems, results in the open-vial/manual mode were similar. In both the automated and manual modes, the SE9500 and Gen•S systems and the SF3000 and HmX were within the specifications stated by their manufacturers. The low-volume systems KX-21 and AcT diff gave results in the closed-vial mode that were within specifications.

Run-to-run precision results (CV%) for the midvolume systems are shown in Table 3. Data for the other systems are similar. No specifications are published for run-to-run precision, but all results were within the ranges provided by the control manufacturer. No calibration shifts or trends were observed on any of the systems being evaluated.

Carryover. For all systems, the percentage carryover was well within the manufacturers' limits. Results are shown in Table 4.

Sample Stability. Sample stability results are shown in Tables 5 and 6. Results shown are for a single representative sample at both room and refrigerated temperatures for the high-volume systems, Gen•S and SE9500. The difference from time 0 is shown for 8, 24, 32, and 56 hours from initial analysis. These times were chosen as representative, although additional testing was done at 4 and 48 hours. Results are considered unacceptable if the difference from time 0 is more than twice the manufacturer's stated precision limit for the parameter. Unacceptable results are indicated on the tables. For the Gen•S, 6 results at room temperature and 3 results at refrigerated temperature at 24 hours or later were outside the limits. At 8 hours, 1 result (mean corpuscular volume [MCV] at room temperature) was outside the limit. For the SE9500, 16 results at room temperature and 9 results at refrigerated temperature at 24 hours or later were outside the limits. At 8 hours, 2 results at room temperature (hemoglobin [HGB] and mean platelet volume [MPV]) and 2 results at refrigerated temperature (platelets [PLT] and MPV) were outside the limit. It should

TABLE 2. Within-Run Precision*

Parameters	High-Volume Systems				Mid-Volume Systems				Low-Volume Systems			
	SE9500	Limits	Gen•S	Limits	SF3000	Limits	HmX	Limits	KX21	Limits	AcT diff	Limits
White blood cells	2.40	3.00	0.85	2.50	1.90	3.00	1.20	2.50	0.13	3.50	1.17	2.50
Red blood cells	0.70	1.50	0.51	0.80	0.70	1.50	0.90	2.00	0.65	2.00	1.16	2.00
Hemoglobin	0.60	1.00	0.22	0.80	0.40	1.50	0.60	1.50	0.33	1.50	0.72	1.50
Hematocrit	0.70	1.50		NS	0.90	1.50		NS	0.64	2.00		NS
Mean corpuscular volume	0.20	1.00	0.56	0.80	0.30	1.50	0.80	2.00		NS	0.35	2.00
Mean corpuscular hemoglobin	1.10	1.50		NS	0.90	1.50		NS		NS		NS
Mean corpuscular hemoglobin concentration	1.10	1.50		NS	1.00	2.00		NS		NS		NS
Platelets	1.10	4.00	1.90	3.20	2.00	5.00	1.10	5.00	2.84	6.00	3.46	5.00
Red cell distribution width	0.50	2.00	1.37	NS	0.90	2.00	1.40	2.50		NS	0.95	2.50
Mean platelet volume	0.80	3.00	1.10	5.00	1.90	3.00	2.10	3.00		NS	1.38	3.00
Neutrophil%	1.3	8.0	2.00†	2.70	1.8	8.0	1.60	3.00		NS	1.34	3.00
Lymphocyte%	2.7	8.0	1.38†	2.70	3.5	8.0	1.80	3.00		NS	3.70	3.00
Monocyte%	7.9	20.0	0.78†	3.00	2.8	20.0	1.40	2.00		NS	20.83	2.00
Eosinophil%	9.8	25.0	0.50†	1.40	11.4	25.0	0.50	1.00		NS		NS
Basophil%	29.6	40.0	0.43†	1.30	‡	40.0	0.50	1.00		NS		NS

*Values are percentage coefficient of variation. NS indicates no manufacturer's specification.
†%Differential.
‡Unable to determine values because of flagged or missing data.

be noted that this same testing was also performed at the other test sites using the mid- and low-volume systems. Similar results and trends were observed.

Method Comparison and Flagging Efficiency. The coefficients of correlation, calculated by regression analysis, for the comparison between each test instrument and the routine laboratory analyzers are shown in Table 7. Excellent correlation was seen for the CBC parameters with coefficients of correlation of >0.95 for all parameters except MCV. The HmX and KX-21 showed lower values, of 0.82 and 0.91, respectively, for this parameter. For the WBC differential parameters, coefficients of correlation were ≥0.90 for neutrophils and lymphocytes. Monocytes, eosinophils, and basophils showed lower coefficients of correlation on the

TABLE 3. Run-to-Run Precision, Mid-Volume Systems*

Parameters	High-Level Control		Mid-Level Control		Low-Level Control	
	SF3000	HmX	SF3000	HmX	SF3000	HmX
White blood cells	1.0	1.9	0.8	1.7	2.2	2.7
Red blood cells	0.8	0.8	1.2	1.2	1.0	0.9
Hemoglobin	0.5	1.4	0.4	0.5	0.9	1.0
Hematocrit	0.8	0.6	1.2	1.1	1.1	1.0
Mean corpuscular volume	0.3	0.4	0.4	0.3	0.7	0.3
Mean corpuscular hemoglobin	0.9	1.5	1.2	1.0	1.0	0.7
Mean corpuscular hemoglobin concentration	0.8	1.4	1.2	1.1	1.5	0.9
Platelets	1.1	2.6	3.6	3.2	12.6	2.6
Red cell distribution width	2.5	1.1	3.1	0.9	2.0	1.1
Mean platelet volume	0.6	1.2	1.5	0.7	3.3	1.0
Neutrophil%	1.6	1.0	2.2	1.2	3.8	1.4
Lymphocyte%	4.8	2.4	3.6	2.5	5.3	2.5
Monocyte%	5.2	3.8	3.2	4.6	5.3	7.5
Eosinophil%	4.2	5.5	10.9	5.6	11.8	5.2
Basophil%†						

*Values are percentage coefficient of variation (CV) for n = 10 analyses.
†Not calculated; very low values do not give meaningful CV.

TABLE 4. Carryover*

	High-Volume Systems				Mid-Volume Systems				Low-Volume Systems			
Parameters	SE9500	Limits	Gen•S	Limits	SF3000	Limits	HmX	Limits	KX21	Limits	AcT diff	Limits
White blood cells	0.1	1.0	0.0	2.0	0.0	3.0	1.0	2.0	0.0	1.0	0.0	2.0
Red blood cells	0.0	1.0	0.3	1.0	0.2	1.5	0.3	1.0	0.2	1.0	0.2	1.0
Hemoglobin	0.0	1.0	0.0	2.0	0.0	1.5	0.0	2.0	0.0	1.0	0.7	2.0
Hematocrit	0.0	1.0		NS		NS		NS		NS		NS
Platelets	0.0	1.0	−1.8	2.0	0.0	1.5	0.0	2.0	0.0	1.0	0.0	2.0

*Values are percentage carryover. NS indicates no specification limits stated by manufacturer.

high- and midvolume systems. The low-volume systems combine these 3 subpopulations, reporting a 3-part differential. Similar results were obtained comparing the WBC differential parameters from each automated system to the manual WBC differential. These results are also shown in Table 7. Overall, the test systems performed comparably to one another.

Truth tables, as a measure of flagging efficiency, for each instrument are shown in Table 8. These results also include an assessment of the flagging for instrumentation currently in use in each laboratory. For mid- and low-volume systems, the efficiency of the test instruments was comparable; however, for high-volume systems, the SE 9500 had a higher false-positive rate and lower overall efficiency.

Technologists' Assessments

The responses to the key-operator survey for the high-volume systems are shown in Table 9. Similar surveys were used for the midvolume and low-volume instrument systems. All key evaluators rated the Beckman Coulter systems higher overall. Surveys based on similar criteria were also given to the staff technologists who ran the analyzers at each hospital. Here again, Beckman Coulter instruments received higher ratings than the Sysmex instruments.

DISCUSSION

At OhioHealth Hospitals, our goal is to equip our hematology laboratories with instrumentation from a single manufacturer.

TABLE 5. Sample Stability: Gen•S*

	Change at 8 h		Change at 24 h		Change at 32 h		Change at 56 h		2 × Precision
Parameter	RT	Refrig	RT	Refrig	RT	Refrig	RT	Refrig	Limit
White blood cells	+0.2	0.0	+0.2	0.0	+0.3	0.0	+0.2	0.0	±0.30
Red blood cells	0.0	+0.04	−0.02	−0.05	−0.04	−0.04	−0.06	−0.05	±0.07
Hemoglobin	0.0	+0.1	−0.1	0.0	0.0	0.0	−0.1	−0.1	±0.2
Hematocrit	+1.1	+10.9	+0.7	−0.3	+1.1	−0.3	+1.3	0.0	± (NS)
Mean corpuscular volume	+2.7†	+1.2	+2.3†	+0.4	+3.9†	+0.1	+4.7†	+1.2	±1.5
Mean corpuscular hemoglobin	+0.1	−0.1	0.0	+0.3	+0.3	+0.3	+0.3	+0.3	± (NS)
Mean corpuscular hemoglobin concentration	−0.8	−0.5	−0.8	+0.3	−1.0	+0.3	−1.3	−0.1	± (NS)
Platelets	+5	−6	+9	−18†	+9	−3	+4‡	−30†	±17
Red cell distribution width	0.0	+0.3	+0.4	−0.1	+0.3	−0.1	+1.5	0.0	± (NS)
Mean platelet volume	+0.6	+0.5	+0.6	+0.7	+1.2†	+0.9†	+1.5†‡	+1.1†	±0.8
Neutrophil%	+0.3	−0.6	+2.5	−1.0	+2.8	+1.3	−3.9	+0.7	±5.2
Lymphocyte%	−1.3	+1.2	−1.2	+1.9	−1.4	+0.3	+3.9	+0.8	±5.2
Monocyte%	+0.8	−0.5	−1.1	−0.7	−1.1	−1.4	+0.8	−1.6	±6.0
Eosinophil%	+0.1	+0.2	−0.1	−0.2	−0.2	−0.1	−0.6	+0.2	±2.8
Basophil%	+0.1	−0.2	−0.1	0.0	−0.1	−0.1	−0.2	−0.1	±2.6
Flags					NRBC		PLT R		

*RT indicates room temperature; Refrig, refrigerated; NS, no specification limits stated by manufacturer; PLT, platelet; NRBC, nucleated red blood cell.

†Unacceptable results. Results are considered unacceptable if the difference from time 0 is more than twice the manufacturer's stated precision limit for the parameter.

‡Results flagged with PLT R flag.

TABLE 6. Sample Stability: SE9500*

Parameter	Change at 8 h		Change at 24 h		Change at 32 h		Change at 56 h		2 × Precision Limit
	RT	Refrig	RT	Refrig	RT	Refrig	RT	Refrig	
White blood cells	–0.26	–0.07	+0.04	+0.08	–0.16	+0.02	–0.06	+0.06	±0.38
Red blood cells	–0.08	–0.01	+0.03	–0.08	+0.02	–0.08	+0.01	–0.07	±0.13
Hemoglobin	+0.4†	0.0	–0.1	0.0	–0.2	0.0	–0.1	+0.1	±0.29
Hematocrit	–0.6	+0.5	NA	–0.4	+3.9†	–0.4	+6.5†	–0.2	±1.2
Mean corpuscular volume	+0.4	+1.3	+6.7†	+0.8	+9.5†	+0.8	+15.2†	+1.0	±1.9
Mean corpuscular hemoglobin	–0.3	+0.1	–0.7	+0.6	–0.3	+0.60	–0.1	+0.7	±1.0
Mean corpuscular hemoglobin concentration	–0.4	–0.5	NA	+0.3	–3.5†	+0.3	–5.1†	+0.4	±1.1
Platelets	–2	+27†	NA	+20†	+29†	+19†	+17	+24†	±19
Red cell distribution width	+0.1	+0.2	–0.5†	0.0	+1.2	+0.1	+1.6†	–0.2	±0.5
Mean platelet volume	+1.3†	+0.9†	+1.2†	+1.2†	+1.7†	+1.4†	+2.5†	+1.5†	±0.6
Neutrophil%	–1.5	+0.3	–3.4	+4.6	–1.6	+5.1	+4.0	+5.7	±8.3
Lymphocyte%	+1.1	–0.3	+1.7	–1.4	+0.5	–2.4	+0.1	–1.2	±5.7
Monocyte%	–0.2	–0.2	+0.7	–3.3	+0.5	–3.5	–5.2	–5.1	±4.4
Eosinophil%	+0.6	–0.2	+0.2	+0.5	+0.4	+0.5	+0.9†	+1.2†	±0.7
Basophil%	0.0	+0.0	+0.8†	–0.2†	+0.2†	+0.3†	+0.2†	0.0	±0.2
Flags			Aged		Atyp/Ab Lymph Aged	Imm Gran Aged	Atyp/Ab Lymph	Atyp/Ab Lymph	

*RT indicates room temperature; Refrig, refrigerated; NA, data not available.

†Unacceptable results. Results are considered unacceptable if the difference from time 0 is more than twice the manufacturer's stated precision limit for the parameter.

Because laboratories at the various sites have different needs, we require the suppliers to have a broad range of products and services. It is important that each laboratory have instrumentation appropriate to its size and testing scope. Consistency of technology, reagent quality, quality-control materials, and a level of customer support are essential for our system.

The use of participative management was essential to our instrument selection process. This attempt was the first by the OhioHealth hospital system to purchase an analyzer that would best fit the needs of all of the hospitals in Central Ohio. It was extremely important that all hospitals have an active role in this process and that all hospital-specific issues were addressed. In any merger of organizations, participation is the key to a truly unified system. Laboratory practices in the past allowed major instrument selection decisions to be made by the management and/or pathologists with little involvement of the staff, the ones who actually need to use the analyzers. In this model, the representatives on the task force included "bench technologists" who have special instrumentation responsibilities and a working supervisor from Doctors North hospital. The manager of the Riverside laboratory acted only in the role of facilitator, helping the group determine the criteria and make sure that all processes were completed. The manager also helped the group to remove road blocks that arose from time to time. However, it was the task force members who actually voted at each pivotal point, twice each time. The first vote was to represent their campuses whereas the second was for their own observations. The team members were responsible for sharing all information with their hospital staffs and bringing back the information to the task force group. This process enabled the staff technologists at all 4 hospitals to become involved with the decision on a personal level. At the conclusion of the evaluation, all technologists felt that their voices had been heard. They now have a vested interest in the success of the implementation.

At the conclusion of each phase, the recommendation of the group was taken to the pathologists and medical directors. The criteria and rationale for our decision were presented to them. In each case, the pathologists and medical directors were impressed with the thoroughness of the evaluation and agreed completely with our recommendations. We included the pathologists and medical directors in the process, as well, and listened to their thoughts and concerns. We provided them with additional in-services by the various technical experts of the companies so that their questions would also be answered. We made a final presentation of the technical data to the laboratory directors. The findings showed comparable results between the 2 manufacturers. The operators' survey focused on the operational issues that were considered important. This information was also presented to the laboratory directors.

At the conclusion of the process, we found that the technical evaluation data and the depth of product line were

TABLE 7. Method Comparison, Coefficient of Correlation

	High-Volume Systems, N = 250 Comparator: Coulter STKS		Mid-Volume Systems, N = 200 Comparator: Sysmex NE8000		Low-Volume Systems, N = 100 Comparator: Cell Dyn 3500	
Parameter	SE 9500	Gen•S	SF 3000	HmX	KX-21	AcT diff
White blood cells	1.00	1.00	0.99	1.00	0.98	0.97
Red blood cells	0.99	1.00	1.00	0.99	0.98	0.98
Hemoglobin	1.00	1.00	1.00	1.00	0.99	0.99
Hematocrit	0.98	0.99	0.99	0.97	0.97	0.97
Mean corpuscular volume	0.88	0.98	0.98	0.82	0.91	0.98
Platelets	0.98	0.99	0.99	0.98	0.98	0.96
Neutrophil%	0.98	0.97	0.91	0.93	0.98	0.91
Lymphocyte%	0.98	0.99	0.93	0.93	0.97	0.94
Monocyte%	0.78	0.49	0.04	0.07		
Eosinophil%	0.98	0.99	0.92	0.96		
Basophil%	0.21	0.17	0.00	0.06		
	Comparator: Manual Differential		Comparator: Manual Differential		Comparator: Manual Differential	
Neutrophil%	0.92	0.93	0.91	0.91	0.93	0.89
Lymphocyte%	0.92	0.93	0.91	0.91	0.93	0.90
Monocyte%	0.50	0.60	0.54	0.58		
Eosinophil%	0.85	0.84	0.80	0.82		
Basophil%	0.09	0.13	0.00	0.17		

comparable and the financial analysis was equivocal. A final comparison chart was made that listed as criteria the most critical issues identified by the evaluators and technologists. Based on all the information collected, the task force recommendation was that Beckman Coulter be chosen to partner with OhioHealth Hospitals for hematology instruments, reagents, and service.

CONCLUSION

When we needed new equipment for the hematology laboratories at OhioHealth Hospitals, we developed a comprehensive decision-making process that utilized participative management techniques. Our objective was to partner with a company that could provide outstanding support for us through hematology laboratory instruments, reagents, and service. Using a 2-phase approach, we first evaluated 5 companies as potential suppliers. After gathering and reviewing the required information, we found that 2 companies were best suited to meet our needs.

Instruments from Beckman Coulter and Sysmex were compared in a side-by-side evaluation. Product range and technical performance were judged to be comparable; both companies have excellent product lines that address different volume and testing-scope issues. Both companies performed well in the technical area across all product lines. The financial analysis was equivocal because both companies worked very well with our Materials Management Department to obtain the best possible price for us. In the end, assessment of the daily operational issues was

TABLE 8. Truth Tables

	High-Volume Systems, N = 260			Mid-Volume Systems, N = 276			Low-Volume Systems, N = 97		
	STKS*	Gen•S	SE9500	NE8000*	HmX	SF3000	CD3000*	AcT Diff	KX-21
True negatives (TN)	228	225	166	225	240	227	81	69	84
True positives (TP)	19	17	18	17	9	10	6	10	2
False negatives (FN)	1	3	1	3	2	4	2	0	4
False positives (FP)	12	15	75	31	25	35	7	17	6
Sensitivity TP/(TP+FN)	0.950	0.850	0.947	0.850	0.820	0.714	0.750	1.000	0.330
Specificity TN/(TN+FP)	0.950	0.938	0.689	0.879	0.906	0.866	0.920	0.802	0.980
Predictive Value Negative TN/(TN+FN)	0.996	0.987	0.994	0.986	0.992	0.983	0.980	1.000	0.950
Predictive Value Positive TP/(TP+FP)	0.613	0.531	0.194	0.354	0.265	0.222	0.460	1.000	0.250
Efficiency (TP+TN)/No.	0.960	0.931	0.708	0.877	0.964	0.958	0.900	0.810	0.890

*Current hematology system.

TABLE 9. Key Operator Survey

Criteria	Sysmex SE9500	Coulter Gen•S
How friendly is the data-management system (DMS) to operate?	Easier to learn: not Windows-NT based	Difficult to learn: based on icons that must be memorized
What problems emerged during the in-house evaluations?	Threw tubes: had to be adjusted by service	Background on reticulocytes was out
How easy is the system to operate compared with other instruments being considered?	Determining correct mode: software does not prompt	Easier to run
How great is the noise level compared with that of the other instruments under consideration? Heat generated?	Quieter; heat not an issue	Noisier; heat not an issue
Is the flagging system easy to interpret?	Yes	Yes
How easy is it to analyze controls?	Must know the file number to look up Levy-Jennings charts	Very easy. Must know the lot number
How easy is it to set up the control files?	Easy	Very easy; everything is on disk
How quickly can data be retrieved from a previous run?	Easy. Can print only 1 copy of a patient report	Easy. Can print multiple copies of a patient report
How easy is the system to use for analyzing a batch of samples?	Easy	Easy
Can the automode easily be interrupted to analyze a STAT microtainer sample in the manual mode?	Yes	Yes
If autosampling is interrupted to use the manual mode, how easy is it to go back into the autosampling mode and how much does this slow down the run?	Not a problem; system does not need to be primed	Not a problem; system does not need to be primed
How easy is it to load and unload sample tubes to the racks?	Possible jams similar to the CA6000	Easy
How easy is it to load different tube sizes into the automode racks?	Easy; the same for both analyzers	Easy; the same for both analyzers
How easy is it to locate tubes, after initial assay is performed, in case the tube is needed for a repeat assay, smear preparation, or another test?	Rack number. Easily done; the same for both analyzers	Cassette position. Easily done; the same for both analyzers
How many jams or problems occurred with the autosampler? How easy were the problems to correct?	Several problems occurred; service needed to come in to correct them	No problems
How easy is it to review multiple samples from the instrument's stored data?	Easy	Easy
How easy is it to transmit multiple samples from stored data at one time to the laboratory information system or printer?	Easy	Easy
How many bar codes were not read? How difficult is it to correct the patient identification?	No problem; the sample can also be identified by rack position	No problem; the sample can also be identified by cassette position
Were short samples detected and how is the operator notified?	No short samples were detected	No short samples were detected
How easy is it to perform the routine maintenance?	Easy, but relatively time consuming	No routine maintenance
Is there exposure to contamination during maintenance?	Some	None
Does the analyzer have real-time diagnostics for troubleshooting?	No	Yes
Does the analyzer have corrective-action messages built into the software or DMS?	Yes	Has video maintenance
Does the DMS have the ability to perform delta checks on patient results, scattergrams, and histograms?	No	Yes

the driving force and favored Beckman Coulter. The laboratory pathologists and directors as well as our staff accepted our recommendation. We have found this process to significantly improve our decision-making ability, because all of the "usual" important issues were addressed, such as technical factors and cost. In addition, the process empowered the staff as participants in the decision-making team.