Arkansas Laboratory Medicine Surveillance Network Surveys 1 and 2 Laboratory Community and Quality Assurance June, 2000

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DH/PHL-LSMN-00/02

Project Background

The Arkansas Department of Health was awarded a grant from the Centers for Disease Control and Prevention (CDC) to establish a data collection network of medical laboratories and survey them for information on the practice of laboratory medicine in hospitals, clinics, and independent laboratories. In meetings held with CDC personnel after the awarding of the grant, it was explained that a major goal of the project was to obtain non-anecdotal data on the operations and quality practices in medical laboratories. Data are needed to support further refinement of the regulations adopted under the Clinical Laboratory Improvement Act (CLIA).

Three other states are also conducting similar programs. The state of Washington was the first state to receive funding for this program, and has been conducting this research since 1996. The Arkansas Department of Health was selected for funding because of the network of county health units that are integrated into the state health agency and a significant rural, medically underserved population.

The first survey was sent out in January, 2000 to 805 hospitals, clinics, and laboratories holding CLIA certificates in Arkansas, and the 94 Arkansas Department of Health Local Health Units (LHUs). A second Survey was sent out in April to a revised list of facilities including all laboratories accredited by the COLA, CAP, and JCAHO programs, as well as clinics and hospitals identified in counties and parishes bordering Arkansas and a selection of clinics not previously surveyed. Follow-up surveys were sent to reference laboratories identified through the questionaires. This survey was sent in two forms – a complete survey to new prospects, and a follow up containing new questions not on the initial survey to respondents from the first survey. Responses were received from 71 out of 75 Arkansas counties and seven other states (Table 1). The instruments was closely modeled after the surveys utilized by the Washington group in order to facilitate the ability to compare the data sets. (LaBeau and Steindal, 1995) Responses were coded and entered in a Microsoft Access database. Analysis was performed using the SPSS statistics package, version 10.0.5. The total response rate was 18.5%.

Data Limitations

The surveys were conducted with the expectations that the sample would not be completely representative. Participants are able to self-select themselves for the data set, and it is expected that this may provide a bias in responses. It would be anticipated, but not demonstrable from this survey, that this bias would result in increased participation by facilities with a greater interest in quality assurance practices. A significant bias may be seen in aggregate data due to the overrepresentation of LHUs (62/277 respondents). These units are largely homogenous and are centrally overseen by the Division of Public Health laboratories. Aggregate data were analyzed with and without the LHUs in order to present a better view of the effect of this overrepresentation.

The original list of laboratories was incomplete, particularly in the area of hospital and reference laboratories. None of the major medical facilities in Little Rock such as the Baptist Medical System or the University of Arkansas Medical School were included in the CDC listings. A number of these were identified and surveys sent to them. This was remedied by obtaining the membership list of the Arkansas Hospital Association and sending a questionaire to all organizations on that list.

A further concern regarding data quality regards the relationship between the Arkansas Department of Health and the laboratory community. A significant part of the sample consists of the LHUs. These units are responsible to the Division of Public Health Laboratories regarding testing matters in that the same quality assurance personnel are involved in both labs. Similarly, a division of the Department of Health has a role in facility licensing. A possibility exists that responses may be tempered by these relationships. In an effort to mitigate this, Dr. Fay Boozman, the Director of the Arkansas Department of Health, wrote a letter emphasizing that this data would not be used for regulatory or other action, and individual laboratory input would remain confidential. That does not eliminate the possibility that some respondents may have tempered their responses to what they thought was the desired answer.

Table 1. Responding Laboratories, by County

County	Responding Facilities	County	Responding Facilities
Arkansas	6	Lafayette	1
Ashley	6	Lawrence	4
Baxter	4	Lee	3
Benton	11	Lincoln	2
Boone	2	Little River	2
Bradley	3	Logan	2
Calhoun	1	Madison	1
Carroll	2	Miller	1
Chicot	4	Mississippi	2
Clark	2	Montgomery	1
Clay	4	Newton	2
Cleburne	2	Ouachita	3
Cleveland	2	Perry	2
Columbia	3	Phillips	2
Conway	1	Pike	3
Craighead	5	Poinsett	4
Crawford	1	Pope	4
Crittenden	3	Pulaski	26
Cross	1	Randolph	1
Dallas	1	Saline	7
Desha	3	Scott	2
Drew	2	Searcy	2
Faulkner	6	Sebastian	14
Franklin	3	Sevier	1
Fulton	2	Sharp	2
Garland	7	St. Francis	3
Grant	1	Stone	1
Greene	4	Union	3
Hempstead	2	Van Buren	3
Hot Spring	2	Washington	8
Howard	2	White	4
Independence	3	Woodruff	2
Izard	4	Yell	5
Jackson	4	Louisiana	15
Jefferson	7	California	1
Johnson	1	Missouri	6
Oklahoma	1	Tennessee	4
Texas	2	Utah	1

Demographics of the Sample

A total of 275 responses containing usable data were received. Of these, 62 were county health units operated by the Arkansas Department of Health. Of the remaining 213, 46 indicated that they would not desire to continue in the network and receive future surveys.

Type of Facility

Sixty-Three of the respondents (22.9%) were classified as Hospitals. Four of these were nursing homes and the remainder were laboratories at regular hospitals.

Of the remainder, 189 facilities (68.7%) were clinics or physician's office laboratories. This classification includes physician's office laboratories (127 or 46.2% of the total) and county health units (62, 22.5%). Two of the physicians were retired. Five of the county health department laboratories was from outside the state, in a neighboring metropolitan area. Eighteen reference laboratories (6.5%) responded, along with 5 (1.8%) other respondents, which included an emergency medical service, a facility with no lab, and three home health organizations.

Testing Volume

Respondents were asked to provide an estimate of the number of tests performed. The responses in the first survey may have been skewed due to a design flaw in the survey instrument that failed to specify whether the time period for determining the volume. Some laboratories did specify whether the volume was per year or per month. Where the latter was specified, the estimate was multiplied by 12 and used as an annual estimate. Data was recoded so as to be consistent with the volume categories used by the state of Washington in their initial survey for reasons of comparability. This was corrected in the second survey by specifying an annual period and having responses returned categorically using the Washington categories. The distribution can be seen in Table 2.

Table 2. Testing Volume of Responding Laboratories

Class (see Figure 1)	Number of Tests	Number of Laboratories	Percentage	Washington State Percentage
1	Less than 2,000	65	31.7	20
2	2,001-10,000	38	18.6	28
3	10,001-25,000	18	8.8	13
4	25,001-50,000	22	10.7	8
5	50,001-75,000	18	8.8	4
6	75,001-100,000	30	14.7	2
7	Greater than 100,000	14	6.8	24

Two hundred and five laboratories provided a usable response to this question. The sample differs from that obtained in the Washington study, with a higher percentage of very small labs (<2,000 tests) and more uniform distribution across the remainder of the categories.

Accreditation Status

Of the laboratories in the sample, 36 (13.9%) reported being accredited by a private organization. When the 54 Arkansas Department of Health county health units that responded are removed from the sample, the percentage rises to 16.3%. Washington reported finding a 26% accreditation rate in their sample. A breakdown of accreditation by the type of laboratory is found in Table 3. Organizations accrediting laboratories in the sample included the American Association of Blood Banks (AARF), American Association of Family Practice (AAFP), American Association of Histocompatability and Immunogenetics (ASHI), the Commission on Office Laboratory Accreditation (COLA), the College of American Pathologists (CAP), the state of Tennessee, the state of California, the state of New York, the military Clinical Laboratory Improvement Program (CLIP), the Joint Commission on Accreditation of Health Care Organizations (JCAHO), the Food and Drug Administration (FDA), and the College of American Respiratory (CARF). Eighty-eight laboratories were accredited by more than one organization other than the HCFA/CLIA program.

Table 3. Accreditation Status by Laboratory Type

Accrediting Body	Hospital Lab	Reference Lab	Office/Clinic Lab	Other	Local Health Units	All Labs (a)
AABB	6 (10.5%)	1 (6.3%)	1 (0.9%)	0	0	8 (3.3%)
ASHI	3 (5.3%)	0	0	0	0	3 (1.2%)
CARF	0	0	1 (0.9%)	0	0	1(0.4%)
CAP	19 (32.7%)	8 (50%)	3 (2.7%)	0	0	30 (12.2%)
COLA	0	1 (6.3%)	22 (19.6%)	0	0	23 (9.3%)
JCAHO	29 (50.1%)	1 (6.3%)	21(18.8	1 (33%)	0	52 (21.1%)
FDA	6 (10.5%)	2 (12.5%)	0	0	0	8 (3.3%)
Tennessee	0	0	1 (0.9%)	0	1 (2.4%)	2 (0.8%)
CLIP	1 (1.8%)	0	0	0	0	1 (0.4%)
CAP+JCAHO	13 (22.8%)	1 (6.3%)	1 (0.9%)	0	0	15 (6.1%)
USEPA	0	2 (12.5%)	0	0	0	2 (0.8%)
AAFP	0	0	1 (0.9%)	0	0	1 (0.4%)
API	0	0	1 (0.9%)	0	0	1 (0.4%)
California	0	1 (6.3%)	0	0	0	1 (0.4%)
New York	0	1 (6.3%)	0	0	0	1 (0.4%)

(a) 247 total.
(b) The Arkansas Department of Health's main laboratory is accredited by FDA, but for food, not medical, testing.

Personnel

Laboratories were asked a series of questions regarding their technical director and the qualifications of testing personnel. Of the responding laboratories, 254 provided a usable response to these questions. Fifty were from Arkansas Department of Health county health units, who have a central director holding a Doctor of Philosophy degree. Laboratory Directors were most commonly Medical Doctors (38.7% of the total) or Board-certified Pathologists (23.7%). Pathologists directed 39/57 hospital laboratories and 13/18 reference laboratories. Medical Doctors served as the director of 88/117 clinic laboratories (excluding county health units). The qualifications of other laboratory directors included a Bachelor's or Master's degree in a laboratory science, medical technician/technologist certification, registered respiratory technician (hospital blood gas lab)and a nursing license (Table 4).

Laboratory directors were generally (64%) the laboratory quality assurance officer in clinic labs aside from the local health units. Hospitals (86%) and reference laboratories (78%) were more likely to have an independent quality assurance officer. This difference is to be expected due to the larger size and more extensive operations in the latter types of labs. Seventy-three laboratories or facilities reported the use of an outside laboratory consultant.

Table 4. Laboratory Director Qualifications

Qualification	Physician's Office/Clinic Laboratory	Hospital Laboratory	Reference Laboratory	Local Health Units	Other Facility
B.S.	3	5	0	0	0
Medical Technician/ Technologist	6	1	0	0	0
Registered Nurse	9	0	0	4	1
Ph.D.	0	3	2	54	0
M.D.	88	7	3	0	0
Pathologist	8	39	13	0	0
M.S.	1	1	0	0	0

The academic backgrounds of testing personnel are presented in Table 5. Numbers represent the number of facilities of the type described using testing personnel with a given credential. Physician office laboratories were found to typically use nursing personnel in testing activities, which is a significant difference from the hospital and reference laboratories, where this is much less common. Reference laboratories and hospitals, on the other hand, almost universally utilize personnel with a background in medical technology. This can be significant as recent studies have found that the use of trained laboratory personnel correlates with improved performance on proficiency testing studies relative to facilities which do not use such personnel (Hurst et al, 1998; Mennemyer and Winkleman, 1993; Winkelman and Mennemyer, 1996).

Table 5. Testing Personnel

Credential	Physician's Office/Clinic Laboratory	Hospital Laboratory	Reference Laboratory	Local Health Units	Other Facility
B.S.	8	14	7	1	0
M.S.	0	6	3	0	0
Ph.D.	0	7	7	1	0
Medical Technician/ Technologist	56	51	17	6	0
Respiratory Therapist	2	4	0	0	0
Nurse	54	6	1	51	1
M.D.	39	19	12	1	0
Other	32	12	3	6	0
Total Responses	**117**	**58**	**18**	**58**	**2**

A linear regression model was run on data received from the Survey 1 laboratories to determine the relationship between laboratory volume and the number of staff members with each qualification. Significant factors included the use of medical doctors (B=.693, ρ=0.000) and medical technicians/technologists (B=.339, ρ=0.000), which showed a positive correlation. Personnel with these qualifications are more likely to be found in larger laboratories. Testing personnel with "other" qualifications, generally non-degreed personnel, were conversely more likely to be found in smaller laboratories (B=-. 119, ρ=0,026). No other significant relationships were noted for other qualifications at the 95% confidence level (Table 6).

Table 6. Regression Analysis of Testing Personnel Qualifications

Factor	Regression Coefficient (B)	Standardized Regression Coefficient (B)	Significance (ρ)	Student t
Constant	-299.44		0.991	-0.011
Medical Technician/Technologist	12961.029	0.693	0.000	9.894
Medical Doctor	37032.662	0.339	0.000	4.956
"Other"	-7332.307	-0.119	0.026	-2.277
B.S.	8019.864	0.039	0.556	0.591
M.S.	66156.287	0.052	0.448	0.764
Ph.D.	-15885.7	-0.022	0.730	-0.346
Nurse	-3265.464	-0.033	0.459	-0.744
Respiratory technician	506.589	0.001	.980	0.025
R^2 = 0.876				
ρ = 0.000				

Laboratory Specialties

A list of classes of laboratory tests was presented in the first survey to the laboratories. Responders were asked to identify tests and the complexity level performed. The Washington state survey, which had the advantage of being able to compare the actual complexity of the testing performed to the responses due to better background data, found that from 25-54% of laboratories did not respond in a way that matched their testing operations. This study lacks the background data available to the Washington group, but did observe numerous indicators that the same situation exists. County Health Units run by the Arkansas Department of Health, for example, perform waived chemistry and hematology testing such as hematocrits or pregnancy tests, and a limited range of moderate complexity microscopic procedures (Gram stain, darkfield microscopy, etc.). Many of these labs reported performing moderate complexity hematology, waived or moderate complexity microbiology, or high complexity microscopy. A number of facilities reported that they held a certificate of waiver, and could not identify the complexity of the tests that they performed. Several other laboratories reported all testing as "moderate" or "high." It is not certain whether this occurred because all tests, regardless of discipline, were of the same complexity, the laboratory checked the highest complexity performed, or the respondent did not understand the classifications. While this study cannot examine the issue with the same depth as in the Washington study, it is evident that the concept of test complexity is poorly understood.

Of 48 non-Arkansas Department of Health facilities reporting whose accreditation status was know, seven held certificates of waiver. One of these reported performing bacteriological testing of moderate complexity, and one reported performing moderate complexity microbiology testing. Two ADH County Health Units reported performing moderate complexity chemistry testing and five reported performing moderate complexity hematology. All of these facilities are operating under a moderate complexity certificate, however the hematology and chemistry procedures performed are waived tests. One County Health Unit reports performing a waived toxicology procedure, as do two other facilities holding a Physician Performed Microscopy certificate. There are no waived toxicology procedures under the CLIA guidelines. These mistakes indicate that it is possible that through misunderstanding of the CLIA guidelines, laboratories may be performing tests beyond their certified level of expertise.

In some cases, responses indicated that the laboratories failed to distinguish between testing performed by their facility and those sent to a reference laboratory. One County Health Unit, for example, reported performing high complexity pathology/cytology. The County Health Units do collect specimens for such testing (Pap smears), but they forward these to a reference laboratory rather than perform the actual test themselves.

This is not a problem unique to this sample set, and does not necessarily affect data quality or patient outcomes, but, as the Washington team noted, "an understanding allows a laboratory to work effectively within the system." The finding that this confusion is not isolated to the Washington sample indicates that the complexity of testing classification under the CLIA regulations may potentially be a source of compliance difficulties, and that a new approach or simplification may be a needed refinement in the regulations.

Laboratory Information Systems

Laboratories were asked to describe the way in which they handle testing data. They were asked whether they used a computer-based Laboratory Information Management System (LIMS) or whether they depended on paper based techniques for tracking laboratory results. Of 254 respondents, 77 (30%) used a LIMS package to manage test data (Table 7). The use was highest in hospitals (35/60 respondents) and reference laboratories (14/17) which is consistent with the hypothesis that larger labs will drive the LIMS market because of a greater need for data management tools. This has been suggested in other studies (Avery *et al*, 2000).

Of the 77 laboratories implementing LIMS systems, 37 were interfaced to patient records. This potentially helps reduce common errors in areas such as order entry, which occurs with up to 5% of tests ordered (Valenstein and Meier, 1999). Plebani and Carraro (1997) found that most errors occur not in the analytical, but rather in the pre- and post- analytical phases of testing due to human error. Technology advances that help reduce the errors involved in data entry and transmission are conducive to reducing these problems.

Table 7. Laboratory Information Management Systems Usage

Facility Type	Manual System	Computer LIMS
Home Health Agency	1	0
Hospital	25	35
Local Health Unit	53	5
Physician Office Laboratory	94	23
Reference Laboratory	3	14

Patient Mix

Laboratories were asked to characterize the insurance types used by their patients by selecting those that were used by at least 25% of their patients. While responses indicate that the facilities may have been approximate in their estimates (some reported as many as four sources, when no more than three were expected) the data is an approximation of the significant sources of reimbursement for services. Two hundred and one responses were obtained.

Table 8. Patient Mix of Respondents (Percent Listing Reimbursement Type)

Reimbursement Type	All Facilities	Hospitals	POLs	Local Health Units	Reference Labs
HMO, PPO, or other private capitated plan	45	38	66	2	66
Medicaid, ARKids First, or other federal or state government plan EXCEPT Medicare or TriCare	54	58	41	84	33
Medicare	66	85	80	16	73
Non-Capitated Indemnity Plans or private payment	38	33	47	22	46
TriCare	2	4	3	0	0
Do Not Know	8	10	3	11	20
Indigent	4	0	2	11	6
Other	2	2	1	2	0

"other" includes Worker's Compensation, Veteran's, Public Health – listed by the respondents.

Significant differences can be seen between the types of facilities. Local/County Health Units are much more likely to have a significant number of reimbursements from government assisted plans, as well as being more likely to see indigent patients, than other facilities. That is consistent with the traditional role of health department facilities as "providers of last resort." Medicare patients – largely elderly, are far more likely to be patients of private facilities. HMO billings are more likely to constitute a significant portion of the patient load in physician office laboratories and reference laboratories than in the hospitals in the sample, an indication of the role these types of plans play in rationing access to hospitals by managing access to care. The data indicates that each type of facility operates in a distinct financial environment, and that the types of patients seen are likely to be different in other ways (income, age, etc.).

Quality Assurance Monitors

The laboratories were surveyed to determine whether they utilized any of fourteen quality assurance monitors, and were given an opportunity to include additional monitors which were not on the list as a note at the end of the question. From the set, 251 responses (250 for "Specimen Acceptability") were obtained. Laboratories provided seven additional monitors. The laboratories as described in Table 9 used the indicators.

The results returned in this survey showed a different response pattern than was seen in the Washington sample. On average, the responses obtained from this survey showed a higher rate of utilization than in the Washington study. Whether this is a real variation or defect in the survey is indeterminate.

Table 9. Use of Quality Assurance Monitors

Technique	Number of Laboratories Utilizing the Monitor in the Arkansas Sample	Percentage of Laboratories Utilizing the Monitor	Washington Percentage of Laboratories Utilizing the Monitor
Calibration Checks	219	88%	N/A
Documentation of Personnel Competency	221	88%	79%
Proficiency Testing Results	224	89%	98%
Incident Reports Related to Laboratory Error	203	81%	64%
Specimen Acceptability	206	82%	67%
Quality Control Results/Control Charting	217	86%	91%
Review of the Final Report	201	80%	64%
Ordering Accuracy	189	75%	50%
Interlaboratory Comparisons	173	69%	56%
Technical Staff Meetings	178	71%	75%
Comparison of Patient History with Results	177	71%	27%
Patient Satisfaction Assessments	149	59%	35%
Comparison of Patient Outcome with Results	144	58%	19%
Evaluation of the Frequency of Repeat Analysis	145	58%	16%
Tissue to Pap Smear Correlation	1	N/A	N/A
Analysis of Turnaround Times	3	N/A	N/A
Workload Analysis	1	N/A	N/A
LIMS Performance	2	N/A	N/A
Crossmatch/Transfusion Ratio	2	N/A	N/A
Lab Charges vs. Tests Ordered	1	N/A	N/A
Chart Audits	1	N/A	N/A

Italics indicate a monitor written in by a laboratory

The relative weight given and frequency of use for each monitor varied with the laboratory type (Tables 9 and 11).

Table 10. Rate of Use by Laboratory Type

Monitor	Overall	Hospital	Physician Office Lab	Local Health Unit	Reference Lab
Proficiency Testing Results	89	98	83	86	100
Documentation of Personnel Competency	88	86	83	95	94
Calibration Checks	88	81	88	97	72
Quality Control Results/Control Charting	86	90	83	86	100
Specimen Acceptability	82	78	82	82	100
Incident Reports Related to Laboratory Error	81	81	78	81	100
Review of Final Report	80	74	82	80	100
Ordering Accuracy	75	75	73	73	100
Technical Staff Meetings	71	72	70	68	94
Comparison of Patient History with Results	71	61	74	78	72
Interlaboratory Comparisons	69	75	65	68	72
Patient Satisfaction Assessments	59	69	56	51	78
Comparison of Patient Outcome with Results	58	46	60	66	56
Evaluation of Frequency of Repeat Analysis	58	42	60	59	89

Office and clinic labs consistently demonstrated lower usage rates for quality control monitors than the reference and hospital laboratories, except for the evaluation of patient histories and outcomes against laboratory results. This is perhaps understood by looking at the environment in which the laboratory work is performed. The laboratory work in most of the responding clinics is performed by the physician or nursing staff, and a higher level of access is available to the patient records than in environments where testing is separated from the patient. It is surprising to find that 60% of reference laboratories indicated that they performed this type of monitor, as these laboratories are the least likely to have access to the patient medical records.

Rankings of utility and rates of utilization were correlated at greater than a 95% confidence limit except for non-County Health Unit clinic/office laboratories and reference (Table 11). Spearman's ρ was used for determining correlations based on the use of the need to correlate ordinal data with ranked data. The reference laboratory results are not conclusive due the very small sample size (5 laboratories). The discrepancy in the physician's office lab is unexpected and no explanation is offered at this time. In general, these results indicate that laboratories tend to use quality assurance monitors that they feel are most appropriate to the testing practices of the laboratory.

County Health Units generally indicated a greater utilization of monitors than other clinic laboratories (13/14 monitors), but a lower opinion of the utility of the monitors (12/14 monitors). Responses from the County Health Units revealed some unexpected results. Out of 52 responding units run by the Arkansas Department of Health, for example, 44 indicated using statistical control charts. None of these, in fact, do testing for which the use of these is appropriate. Whether this is a misunderstanding of the survey instrument, an artifact of the fact that the clinic labs are reporting units of the surveying office or a revelation of fundamental misunderstandings of quality assurance practices cannot be determined by these results alone.

Table 11. Value of Feedback from Quality Assurance Monitors

Documentation of Personnel Competency — Rank of Value of Feedback (%) (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	12	4	6	16	29	33	1
Hospital Labs	60	12	2	10	20	38	17	2
Physician Office Labs	113	16	4	5	12	29	33	< 1
County Health Units	59	5	3	3	22	20	46	0
Reference Labs	18	6	6	6	17	22	44	0
Other Labs	1	100	0	0	0	0	0	0

Incident Reports related to Lab Error — Rank of Value of Feedback (%) (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	19	4	5	18	22	31	< 1
Hospital Labs	60	17	2	7	17	28	27	2
Physician Office Labs	113	21	3	6	17	21	31	< 1
County Health Units	59	19	12	3	25	17	24	0
Reference Labs	18	0	0	0	11	17	72	0
Other Labs	1	100	0	0	0	0	0	0

Comparison of Patient History to Lab Results — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	29	3	6	19	18	24	< 1
Hospital Labs	60	40	3	7	18	17	13	2
Physician Office Labs	113	27	2	4	18	22	27	< 1
County Health Units	59	22	3	7	20	14	34	0
Reference Labs	18	33	6	11	22	11	17	0
Other Labs	1	100	0	0	0	0	0	0

Calibration Checks — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	13	1	2	15	17	51	< 1
Hospital Labs	60	20	0	2	20	25	32	2
Physician Office Labs	113	12	< 1	3	9	13	61	2
County Health Units	59	3	3	0	27	19	47	0
Reference Labs	18	28	0	11	6	6	50	0
Other Labs	1	0	0	0	0	0	100	0

Table 11. Value of Feedback from Quality Assurance Monitors (continued from previous page)

Interlaboratory Comparison — Rank of Value of Feedback (Percent) (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	31	4	4	20	20	22	0
Hospital Labs	60	25	3	7	22	20	23	0
Physician Office Labs	113	35	4	3	14	25	20	0
County Health Units	59	32	5	3	29	8	22	0
Reference Labs	18	28	0	0	17	28	28	0
Other Labs	1	0	0	0	0	0	100	0

Ordering Accuracy — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	25	3	4	16	21	31	0
Hospital Labs	60	27	3	7	17	27	20	0
Physician Office Labs	113	27	3	4	11	22	35	0
County Health Units	59	14	3	2	29	20	32	0
Reference Labs	18	0	6	0	17	6	72	0
Other Labs	1	100	0	0	0	0	0	0

Comparison of Patient Outcome to Lab Results — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	43	1	4	19	14	18	< 1
Hospital Labs	60	55	2	5	23	7	8	0
Physician Office Labs	113	40	< 1	4	14	19	20	1
County Health Units	59	34	2	5	20	14	25	0
Reference Labs	18	44	0	0	33	6	17	0
Other Labs	1	100	0	0	0	0	0	0

Proficiency Testing Results — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	11	2	1	7	18	61	< 1
Hospital Labs	60	2	2	0	3	23	68	2
Physician Office Labs	113	17	3	2	9	16	52	1
County Health Units	59	10	3	2	15	14	56	0
Reference Labs	18	0	0	0	0	11	89	0
Other Labs	1	100	0	0	0	0	0	0

Table 11. Value of Feedback from Quality Assurance Monitors (continued from previous page)

Review of Final Report — Rank of Value of Feedback (%) (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	20	2	6	12	20	39	< 1
Hospital Labs	60	27	2	12	17	13	30	0
Physician Office Labs	113	19	< 1	3	12	19	45	< 1
County Health Units	59	20	2	7	10	29	32	0
Reference Labs	18	0	11	0	6	22	61	0
Other Labs	1	100	0	0	0	0	0	0

Meetings of the Technical Staff — Rank of Value of Feedback (%) (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	29	4	7	16	24	19	< 1
Hospital Labs	60	27	0	13	13	28	17	2
Physician Office Labs	113	30	6	6	14	26	18	0
County Health Unit	59	37	5	3	19	19	17	0
Reference Labs	18	6	0	6	28	22	39	0
Other Labs	1	100	0	0	0	0	0	0

Specimen Acceptability — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	250	18	4	4	17	18	38	1
Hospital Labs	60	22	2	5	22	20	28	0
Physician Office Labs	113	17	4	6	14	19	36	0
County Health Units	59	17	2	2	22	20	37	0
Reference Labs	18	0	11	0	0	6	78	6
Other Labs	2	100	0	0	0	0	0	0

Frequency of Repeat Analysis — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	43	7	7	15	18	10	0
Hospital Labs	60	58	8	3	12	12	7	0
Physician Office Labs	113	40	4	6	9	26	13	0
County Health Units	59	41	8	12	24	8	4	0
Reference Labs	18	11	11	11	22	28	17	0
Other Labs	1	100	0	0	0	0	0	0

Table 11. Value of Feedback from Quality Assurance Monitors (continued from previous page)

Quality Control Results/ Control Charts — Rank of Value of Feedback (Percent) (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	14	3	3	11	16	55	0
Hospital Labs	60	10	0	3	1	28	62	0
Physician Office Labs	113	17	<1	4	7	15	58	0
Local Health Units	59	14	3	2	29	20	32	0
Reference Labs	18	0	0	0	0	0	100	0
Other Labs	1	100	0	0	0	0	0	0

Patient Satisfaction Assessments — Rank of Value of Feedback (1=little value, 5=very valuable)

Type of Laboratory	N	Not used	1	2	3	4	5	Used, no ranking
All Labs	251	41	6	8	15	16	14	0
Hospital Labs	60	30	7	13	22	20	8	0
Physician Office Labs	113	44	6	5	12	19	12	0
County Health Units	59	49	3	8	14	8	17	0
Reference Labs	18	22	11	0	17	11	39	0
Other Labs	1	100	0	0	0	0	0	0

What Makes a Quality Laboratory?

The surveyed facilities were asked a series of questions on the second survey designed to probe how they defined a quality laboratory, and what criteria they used to select a reference laboratory for their own use. Furthermore, these questions sought to determine how decisions were made as to where a laboratory test was referred. These questions were designed based on the work of the Washington group and a Clinical Laboratory Management Association study conducted by Zinn and Zalakowski (1999) that used a Delphi panel to develop a set of laboratory performance indicators.

Factors in choosing a Reference Laboratory

Laboratories were asked to choose the five most important factors in they considered in choosing the reference laboratory that they use from a list of 19 factors, and then to rank these factors from 1-5, with 1 being the most important factor. 159 facilities responded. For hospitals and physician office labs, the same five factors – turnaround times, cost, laboratory reputation, courier services, and the available of on-site printing of reports – were the five most frequently listed factors. These responses were essentially identical to those observed by LaBeau et al (1999). Turnaround times and cost were also among the top five reasons cited by county health units, with courier services ranking sixth. The top reason cited by these units was that the choice was mandated by superiors within the state health department. Independent labs cited cost, availability of staff for problem resolution, turnaround time, proximity to their facility, and a streamlined system for ordering and billing as their top five reasons. Turnaround times and costs are consistently among the top reasons all groups used for selecting the reference laboratory (Table 13).

Aside from the rate of citation, the importance of the factor was judged by examining the rate at which the factor was chosen as the most important factor by the surveyed facilities. Factors ranked as "most important" by at least 20% of labs in a group are described in Table 12. This analysis reveals that, in addition to the factors previously noted, the decisions of organizational superiors also plays a significant role in how all types of facilities, except the independent laboratories, make decisions on which laboratories to use.

Although managed care requirements were a minor factor, the response was again greater than that of the Pacific Northwest sample, with 16% reporting it versus about 13% in the other study. As in the Washington sample, these requirements fell predominately in the physician's office laboratories, and, interestingly, the county health units.

Table 12. "Most Important Factors"

All Facilities	Hospitals	Physician Office Laboratories	County Health Units	Independent Laboratories
Mandated by Superiors in the Organization (24%)	Lab Reputation (33%)	Cost Per Test (30%)	Mandated by Superiors in the Organization (42%)	Cost Per test (31%)
Cost Per test (23%)	Mandated by Superiors in the Organization (21%)	Mandated by Superiors in the Organization (21%)		
Lab Reputation (23%)				

Table 13. Factors in selecting a Reference Lab (% of labs listing)

Factor	All Facilities	Hospital Labs	Physician Office Labs	County Health Units	Reference Laboratories
Turnaround Times	65	76	68	42	54
Cost Per Test	60	64	65	25	77
Laboratory Reputation	51	62	46	13	23
Courier Services	47	60	50	25	23
On-site Printing of Test Results (including faxing)	37	52	39	17	15
Mandated by Superiors in the Organization	35	40	25	71	8
Availability for Problem Resolution	28	19	25	25	62
Frequency of Pickup	26	19	34	29	15
Proximity to the Facility	23	17	23	29	31
Mandated by a Managed Care Organization	16	5	20	21	8
No Charge for Supplies	16	14	18	17	8
Streamlined Ordering and Billing	13	7	16	0	31
Assistance with Interpreting Results	11	7	13	4	23
Frequent Contact with a Sales Representative	11	19	10	0	8
Custom Profiles to meet Client needs	8	2	15	0	0
Support for Testing in the Client's Laboratory	7	10	4	8	15
On-Site Specimen Collection Services	6	2	5	17	0
Report Design and Clarity	4	0	4	8	0
Patient Convenience	6	12	4	8	0

Outsourcing In-House Tests

Laboratories were asked how frequently they sent patient specimens to an outside laboratory for testing which they normally performed in-house. Responses were on a 4 point Likert scale, with 0=never, 1=rarely, 2=sometimes, 3=often or frequently. Responses are noted in Table 14. The strongest responses are for "Mandated by a Managed Care Contract" and "The Test is Part of a Battery containing Other Tests We Don't Perform," in terms of laboratories which cite the reason as being utilized "often or frequently."

These findings are somewhat different than those reported by Pacific Northwest laboratories in an identical study (LaBeau, et al, 1999). The Washington Group findings were that 18% of laboratories reported that they "sometimes" or "often" were forced to send out samples based on a managed care contract, and that this factor was the fifth most common reason to send out samples that could be tested in-house. Thirty one percent of the this sample reported that they were required to do so by a managed care contract, second only to the test being included in a battery containing non-performed tests. The response is most noticeable in the physician office laboratories and independent laboratories. The physician office laboratories are likely to face the

greatest impact from managed care. Centralization of testing tends to move tests from these laboratories to hospital and/or independent laboratories. The acute needs of hospitals will buffer those laboratories from some of the managed care practices that other laboratories are forced to deal with. County health units, treating patients largely without regard to insurance, are somewhat insulated from these forces.

Table 14. Reasons to Outsource Samples for Tests Performed In-House

Abnormal Result, Confirmation Needed

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	26	46	25	3	0
Hospital	41	22	59	12	7	0
Physician Office Laboratory	86	17	48	34	1	0
County Health Unit	23	65	9	22	4	0
Independent Laboratory	13	31	62	8	0	0

Regular Testing Personnel are Absent

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	65	24	9	2	0
Hospital	41	80	15	2	2	0
Physician Office Laboratory	86	55	30	13	2	0
County Health Unit	23	83	4	13	0	0
Independent Laboratory	13	54	46	0	0	0

Ran Out of Reagents, Controls, or Testing Materials

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	44	48	8	1	0
Hospital	41	22	93	10	0	0
Physician Office Laboratory	86	45	47	7	1	0
County Health Unit	23	78	17	4	0	0
Independent Laboratory	13	38	46	15	0	0

Lab Result was Indeterminate or Difficult to Interpret

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	31	47	21	1	0
Hospital	41	15	68	17	0	0
Physician Office Laboratory	86	31	43	24	1	0
County Health Unit	23	57	17	26	0	0
Independent Laboratory	13	31	62	8	0	0

Physician Questions the Accuracy of the Result

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	37	55	7	1	0
Hospital	41	32	66	2	0	0
Physician Office Laboratory	86	31	60	6	1	0
County Health Unit	23	78	9	13	0	0
Independent Laboratory	13	23	69	8	0	0

Table 14. Reasons to Outsource Samples for Tests Performed In-House (continued)

Mandated by a Managed Care Provider or Insurance Contract

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	49	18	18	13	2
Hospital	41	61	24	5	7	0
Physician Office Laboratory	86	33	19	28	19	2
County Health Unit	23	20	4	9	0	0
Independent Laboratory	13	54	23	8	15	0

Instrument Problem or Failure

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	29	45	26	0	0
Hospital	41	22	51	27	0	0
Physician Office Laboratory	86	21	50	29	0	0
County Health Unit	23	70	13	17	0	0
Independent Laboratory	13	31	54	15	0	0

Physician Wants Confirmation by a More Precise Method

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	32	46	20	2	0
Hospital	41	24	63	12	0	0
Physician Office Laboratory	86	23	47	28	2	0
County Health Unit	23	74	4	13	9	0
Independent Laboratory	13	38	62	0	0	0

Result is Needed Stat and We Don't Perform on That Basis

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	69	20	9	2	0
Hospital	41	78	20	2	0	0
Physician Office Laboratory	86	65	23	9	3	0
County Health Unit	23	83	4	13	0	0
Independent Laboratory	13	46	23	23	8	0

Verify Laboratory Test Result

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	28	47	22	3	0
Hospital	41	27	56	15	2	0
Physician Office Laboratory	86	24	48	27	1	0
County Health Unit	23	48	13	26	13	0
Independent Laboratory	13	23	69	8	0	0

Table 14. Reasons to Outsource Samples for Tests Performed In-House (Continued)

Patient Requested a Different Laboratory

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	67	27	5	1	0
Hospital	41	73	24	2	0	0
Physician Office Laboratory	86	59	34	6	1	0
County Health Unit	23	78	9	9	4	0
Independent Laboratory	13	77	23	0	0	0

Test is Part of a Less Expensive Battery

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	67	21	7	4	1
Hospital	41	68	22	5	5	0
Physician Office Laboratory	86	63	23	9	1	1
County Health Unit	23	78	9	9	4	0
Independent Laboratory	13	77	23	0	0	0

Test is part of a Battery Containing Other Needed Tests That We Don't Perform

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	39	22	26	12	1
Hospital	41	16	32	27	1	0
Physician Office Laboratory	86	33	21	28	17	1
County Health Unit	23	65	9	13	13	0
Independent Laboratory	13	38	46	15	0	0

The Sample was Collected Too Late to Analyze Before the End of a Shift

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	71	23	6	1	0
Hospital	41	93	7	0	0	0
Physician Office Laboratory	86	59	33	7	1	0
County Health Unit	23	83	9	9	0	0
Independent Laboratory	13	62	31	8	0	0

Result Exceeded the Instrument Range

		Response (%)				
Facility Type	N	0	1	2	3	US
All Facilities	163	50	36	12	1	0
Hospital	41	56	37	7	0	0
Physician Office Laboratory	86	37	45	17	0	0
County Health Unit	23	74	9	9	9	0
Independent Laboratory	13	77	23	0	0	0

Total Quality Indicators

Facilities were asked to choose five factors from a list of 25 that they felt were most important to the total quality of service provided by a medical laboratory, and then rank those five from 1 to 5 with “1” being the most important factor. A variety of factors were chosen from areas representing the data quality, service, and economic areas, and the concept of total quality was emphasized in the question. This was done to attempt to ascertain what was considered an “optimum” laboratory by the respondents as well as to make the respondents choose from among these different values.

Responses were similar for all types of facilities (Table 15). “Assuring the accuracy of test results” ranked first or second in total responses for all types of laboratories, listed by 83% of all facilities and not less than 75% in any category. “Timely notification of panic values or other abnormal results” ranked first or second for all categories except county health units, for which it ranked third. At least 50% of facilities in each category ranked this indicator. “Use of quality control and proficiency testing”, “short turnaround times”, and “personnel training” were also among the top five choices for all categories of facilities. This demonstrates a surprising unity of values among the various categories as to what makes a quality laboratory. Personnel in medical testing agree that a quality laboratory should produce reliable data quickly using adequately trained personnel, monitor data quality, and make sure that abnormal results are promptly brought to the caregivers attention. These values are also consistent with the major components of the CLIA regulations, indicating that the general approach of the program may be correct and that problems that occur may, as has been previously suggested, arise from the implementation rather than the structure of the regulations (Bachner, 1998).

Table 15. Indicators of Total Quality in the Laboratory
(percent listing indicator in their top 5)

Indicator	All Facilities	Hospitals	Physician Office Laboratories	County Health Units	Independent Laboratories
N=	191	84	47	44	16
Assuring the Accuracy of Laboratory Results	83	94	79	77	100
Timely Notification of Panic Values or Abnormal Results	71	77	77	59	69
Use of Quality Control and Proficiency Testing	53	53	58	41	63
Short Turnaround Times	50	62	42	59	38
Personnel Training	44	40	39	48	56
Patient Satisfaction with Phlebotomy Staff	28	21	31	27	31
Reduced Cost of Testing	26	21	15	18	19
Equipment Maintenance	21	21	23	27	6
Predictable Turnaround Times	16	15	17	16	13
Computerized Reporting of Laboratory Results	13	19	7	16	13
Internal and External Audits of the Laboratory Quality System	12	11	11	7	38
Availability of Point of Service Testing	12	6	13	16	6
Rapid Access to Laboratory Results	11	11	12	11	6
Monitor Patient Satisfaction	10	10	6	18	6
Monitor Physician/Provider Satisfaction	8	9	7	7	19
Usage of State-of-the-Art Equipment	9	13	4	14	13
Clarity and Ease of Use of the Test Order Form	8	0	11	11	6
Minimizing Repeat and/or High Cost Testing	7	2	10	9	0
Use of a Test Menu to Discourage Inappropriate Testing	5	9	5	2	0
Mechanisms for Specimen Tracking	4	2	5	7	19
Provision of Educational Materials on New Tests	4	2	4	7	0
Presentation of Laboratory Data in Reports	2	6	1	0	0

Reasons to Add a New Test

Laboratories were queried as to the impact of ten factors upon the decision to add a new test at their facility. One hundred ninety three responses were received. Responses are detailed in Table 15.

All types of laboratories chose in aggregate the “Level of Need for a Test” as the strongest factor for adding a test. The only other factor approaching the same overall strength was the “Cost of the Test.” Physician’s office laboratories and independent laboratories paid close attention to reimbursement rates and the overall cost of the test as accompanying factors. County health units placed a significant emphasis on the technical ability of their staff to perform the test, with a strong influence from higher echelons in their organization. The cost of the equipment received a significantly weaker response from this type of laboratory than the other types.

Hospitals gave a strong response to the cost of the equipment, but not as much to the cost of the test or the reimbursement rates. Ringel et al (1999) surveyed a national sample of hospital Chief Financial Officers regarding attitudes toward laboratories and discovered that, although generally viewed as a revenue generator, there was an emphasis on increasing efficiency and cutting costs as if the laboratory was a cost center. This is consistent with the response from this sample. If the laboratory is treated as a cost center, reduced initial costs would be more important than inputs in the conceptual model under which they are managed. The greater emphasis on reimbursement and overall costs seen in the independent and physician’s office laboratories are more consistent with a conceptual model where laboratory services are a revenue generator. Since net revenue is related to the reimbursement rate minus the cost, both factors play a role in determining the economic return from the test.

A correlation of the types of significant reimbursement plans with the reasons for implementing a new test also demonstrate interesting correlations. The data obtained from asking for facilities to choose “significant” (>25% of patients) provider types was correlated to the facility responses to this question using the tau-b correlation statistic (Table 16). Laboratories with significant numbers of patients using managed care plans, Medicare, or unknown insurance demonstrated correlation to the cost and reimbursement rates that were statistically significant at the 90% confidence limit. For Medicare and managed care situations, these were positively correlated, indicating that they were more likely to consider these factors in establishing a new test. Facilities treating a significant number of patients with “unknown” coverage were negatively correlated. These facilities are less likely to consider the economic factors. This difference is easily explained. Facilities such as county health units, military or veteran’s hospitals, or charity hospitals and clinics which treat patients without regard to insurance are likely to be less concerned with the economics of the reimbursement due to differences in management philosophy.

Laboratories dependent on Medicare patients demonstrate a significant relationship with the overall cost of the test, unlike the managed care and “unknown” laboratories. While the laboratories seeing significant numbers of “unknown” patients have a mission orientation that is unrelated to the cost of the test, the difference between the other two types of reimbursement is not as immediately obvious. It would be expected that overall cost would be a significant factor with the laboratories dealing with significant numbers of managed care patients due to the limitations of capitation, while the total cost would be less significant for non-capitated Medicare patients as long as the reimbursement rate was high enough to cover the cost. Several studies (Keffer, 1995, Chernew et al 1998) suggest that cost is a significant determinant in the adoption of new medical technologies by managed care organizations, even though the net effect of the test may be to increase health care costs. Chernew and colleagues note that “if HMOs decrease the margin between price and cost for health care services…the effects on system expenditure would be even greater than those reported.” This is apparently the effect seen in the case of facilities with significant numbers of HMO patients. The margin between reimbursement rate and cost becomes more critical than the total cost of the test. Tighter margins make investment decisions

more critical. Benge and colleagues (1997), in a study of the Vanderbilt University Medical Center, found that decreased use of tests realizes relatively small cost savings and can actually increase costs due to large fixed costs in the laboratory that are then spread over a decreasing number of specimens. The tight margins and utilization controls associated with managed care help us understand the observed correlation. Cost of the instrumentation and equipment become more important because the size of the fixed costs of the test are more critical due to the utilization controls common to managed care. A large fixed cost exposes the laboratory to a higher level of financial risk than in a non-managed environment. Higher rates of utilization mitigate some of the risk associated with the fixed costs, making the total cost of the test more important relevant to the fixed costs. This is consistent with the findings observed in this study.

A broader concern would be the impact of these decisions on access to care for vulnerable populations. Trude and Colby (1997) note that a decline in payments levels on the Medicare fee schedule can result in a reduction in access to health care after fee reductions. This was a particular problem among African-American and low income beneficiaries, and beneficiaries lacking supplemental insurance – a population of some significance in Arkansas and the surrounding areas surveyed in this study. The finding that cost plays a role in determining what services to offer for practices with significant numbers of Medicare patients is therefore troubling.

Table 16. Decision Factors in Adding a New Test

Level of Need for a Test

Facility Type	Number Respondents	Response (%) (1=No Impact, 5=Great Impact) No Response	1	2	3	4	5
All Facilities	193	2	2	1	8	14	73
Hospitals	47	0	0	2	10	9	79
Physician Office Labs	88	1	2	1	8	16	70
County Health Units	42	7	2	0	5	17	69
Independent Labs	16	0	0	0	13	13	75

Decision of a Parent Organization

Facility Type	Number Respondents	Response (%) (1=No Impact, 5=Great Impact) No Response	1	2	3	4	5
All Facilities	193	5	32	9	17	15	24
Hospitals	47	4	43	17	15	13	9
Physician Office Labs	88	13	37	7	16	13	20
County Health Units	42	2	7	7	17	19	48
Independent Labs	16	0	31	6	19	19	25

Cost of Equipment Needed to Perform the Test

Facility Type	Number Respondents	Response (%) (1=No Impact, 5=Great Impact) No Response	1	2	3	4	5
All Facilities	193	3	3	2	12	25	55
Hospitals	47	4	2	4	15	19	55
Physician Office Labs	88	2	2	1	8	21	64
County Health Units	42	7	5	0	17	36	36
Independent Labs	16	0	0	0	13	16	56

Reimbursement Rates for the Test

Facility Type	Number Respondents	Response (%) (1=No Impact, 5=Great Impact) No Response	1	2	3	4	5
All Facilities	193	2	7	8	22	22	39
Hospitals	47	0	6	6	28	32	28
Physician Office Labs	88	1	5	5	17	17	57
County Health Units	42	5	14	17	24	24	17
Independent Labs	16	0	0	13	25	19	44

Table 15. Decision Factors in Adding a New Test (continued)

Technical Ability of the Staff to Perform the Test

		Response (%) (1=No Impact, 5=Great Impact)					
Facility Type	**Number Respondents**	**No Response**	**1**	**2**	**3**	**4**	**5**
All Facilities	193	3	8	7	14	26	86
Hospitals	47	4	11	17	17	21	30
Physician Office Labs	88	2	10	2	13	31	41
County Health Units	42	5	2	5	12	17	60
Independent Labs	16	0	6	13	19	31	31

Need for a Rapid Result from the Test

		Response (%) (1=No Impact, 5=Great Impact)					
Facility Type	**Number Respondents**	**No Response**	**1**	**2**	**3**	**4**	**5**
All Facilities	193	3	3	6	26	32	30
Hospitals	47	2	4	6	19	43	26
Physician Office Labs	88	2	3	6	32	28	28
County Health Units	42	5	14	17	24	24	17
Independent Labs	16	0	0	13	25	19	44

Lack of an Alternate Provider for the Test

		Response (%) (1=No Impact, 5=Great Impact)					
Facility Type	**Number Respondents**	**No Response**	**1**	**2**	**3**	**4**	**5**
All Facilities	193	6	17	15	20	21	20
Hospitals	47	4	19	17	13	26	21
Physician Office Labs	88	6	18	19	20	19	17
County Health Units	42	10	12	2	24	24	29
Independent Labs	16	17	19	19	31	13	13

Cost of the Test

		Response (%) (1=No Impact, 5=Great Impact)					
Facility Type	**Number Respondents**	**No Response**	**1**	**2**	**3**	**4**	**5**
All Facilities	193	3	3	4	22	22	46
Hospitals	47	2	4	6	21	26	40
Physician Office Labs	88	2	2	3	16	20	55
County Health Units	42	9	2	2	36	24	26
Independent Labs	16	0	6	0	19	19	56

Table 16. Decision Factors in Adding a New Test (continued)

Stability of the Specimen

Facility Type	Number Respondents	Response (%) (1=No Impact, 5=Great Impact) No Response	1	2	3	4	5
All Facilities	193	4	4	10	22	27	34
Hospitals	47	4	4	13	26	34	19
Physician Office Labs	88	2	5	11	15	32	41
County Health Units	42	10	2	5	26	38	21
Independent Labs	16	6	0	13	31	19	31

Distance to an Alternative Test Provider

Facility Type	Number Respondents	Response (%) (1=No Impact, 5=Great Impact) No Response	1	2	3	4	5
All Facilities	193	7	18	18	19	27	15
Hospitals	47	6	32	21	21	9	11
Physician Office Labs	88	6	16	19	15	31	23
County Health Units	42	9	2	6	28	19	21
Independent Labs	16	6	25	31	6	25	6

Table 17. Correlation between Patient Reimbursement Plans and New Test Justifications

	Insurance Type				
Factor	Medicaid	Medicare	HMO	Fee For Service	Do Not Know
Level of Need for a test					
Kendall's tau-b	-0.043	0.044	0.047	-0.003	0.014
Significance	0.536	0.524	0.500	0.967	0.838
Decision of a Parent Organization					
Kendall's tau-b	*0.131*	*-0.315*	*-0.125*	-0.087	0.044
Significance	*0.042*	*0.000*	*.052*	0.178	0.497
Cost of Equipment					
Kendall's tau-b	0.015	*0.197*	*0.118*	-0.042	*-0.154*
Significance	0.825	*0.004*	*0.080*	0.531	*0.023*
Reimbursement Rate					
Kendall's tau-b	-0.048	0.303	0.140	0.052	-0.175
Significance	0.462	0.000	0.033	0.433	0.008
Staff Technical Abilities					
Kendall's tau-b	-0.008	-0.045	0.044	-0.012	-0.048
Significance	0.901	0.496	0.502	0.858	0.470
Need for a Rapid Result					
Kendall's tau-b	0.047	-0.025	0.018	-0.016	*-0.117*
Significance	0.474	0.703	0.781	0.808	*0.076*
Lack of an Alternate Provider					
Kendall's tau-b	0.069	*-0.117*	*-0.145*	*0.036*	-0.098
Significance	0.283	*0.066*	*0.023*	*0.574*	0.125
Cost Per Test					
Kendall's tau-b	0.003	*0.155*	0.021	0.013	-0.080
Significance	0.965	*0.075*	0.747	0.849	0.227
Stability of the Specimen					
Kendall's tau-b	0.005	*0.116*	-0.052	0.033	-0.200
Significance	0.939	*0.075*	0.426	0.616	0.002
Distance to an Alternate Test Provider					
Kendall's tau-b	0.043	-0.104	*-0.113*	0.092	*-0.138*
Significance	0.500	0.104	*0.077*	0.151	*0.030*

Significant responses are noted in italics and shaded cells.

Consequences of Not Performing Tests On-Site

Laboratories were asked to describe what they viewed as the consequences of not performing a particular test at their site. Eight consequences were listed, with an option to choose “other” and list additional reasons. Each was ranked on a 4 point Likert scale from “little or no consequence” to “severe consequences.” Facilities were able to choose “not applicable to my laboratory for each consequence.

Consequences directly related to patient care and the quality of the specimen elicited the strongest concern. Concerns over the delay of treatment were the strongest. Concern over result accuracy was mixed, with somewhat more facilities rating it as of little or no consequence than of great consequence. This may be indicative of trust in the reference labs used by the respondents.

Additional administrative burdens such as follow-up phone calls and paperwork were not seen as serious burdens by the responding facilities.

One respondent noted that a clinic needs to have adequate capabilities to address acute patient needs, and that if centralization of testing does not allow for these capabilities, patient care is compromised.

Table 18. Consequences of Performing a Test Off-site

Patient would have to go to another lab to submit a specimen

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	185	11	11	16	28	32
Hospitals	44	11	18	16	11	43
Physician Office Laboratories	83	14	11	18	33	27
County Health Units	43	5	16	16	38	23
Independent Laboratories	15	7	7	7	20	60

Patient would have to return for another office call

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	184	14	15	21	21	29
Hospitals	44	23	16	14	5	43
Physician Office Laboratories	83	14	14	24	26	20
County Health Units	42	7	19	21	29	24
Independent Laboratories	15	7	7	20	13	53

A Delay in treatment would occur

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	185	6	12	24	44	14
Hospitals	44	9	18	18	36	18
Physician Office Laboratories	83	6	11	28	48	7
County Health Units	43	7	9	19	44	21
Independent Laboratories	15	0	7	33	40	20

Table 18. Consequences of Performing a Test Off-site (continued)

Extra paperwork would be required to evaluate and chart lab results

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	185	29	24	20	5	22
Hospitals	44	27	27	9	2	34
Physician Office Laboratories	83	35	19	25	7	13
County Health Units	43	23	30	23	2	21
Independent Laboratories	15	20	27	13	7	33

Result accuracy would be compromised

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	185	30	10	17	21	22
Hospitals	44	32	10	14	10	36
Physician Office Laboratories	83	31	11	18	27	11
County Health Units	43	28	12	16	21	23
Independent Laboratories	15	27	0	13	20	40

A phone call follow-up would be necessary

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	185	30	22	19	5	23
Hospitals	44	30	20	11	0	39
Physician Office Laboratories	83	34	25	20	6	13
County Health Units	43	23	16	26	12	23
Independent Laboratories	15	27	27	13	0	33

The specimen would be compromised due to distance or frequency of pickup

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	185	19	12	14	28	26
Hospitals	44	18	9	14	23	36
Physician Office Laboratories	83	24	14	14	29	16
County Health Units	43	14	7	16	33	30
Independent Laboratories	15	13	27	7	20	33

Table 18. Consequences of Performing a Test Off-site (continued)

Cost to the patient would be higher

		Percent Responding				
Consequence	N	0	1	2	3	Not Applicable
All Facilities	185	16	17	24	24	19
Hospitals	44	20	27	23	5	25
Physician Office Laboratories	83	18	14	33	27	8
County Health Units	43	12	9	9	42	28
Independent Laboratories	15	0	20	27	20	33

Discussion

Several major points observed in this study may have a bearing on policy issues. First, the laboratory community poorly understands the concept of test complexity. As a cornerstone of the CLIA regulatory scheme, this does not bode well for the implementation of the regulations on a practical level. In order to comply with the regulations, laboratories need to understand the requirements that the regulations place on them. While a strong educational effort may overcome this difficulty, it would also be wise for the appropriate federal authorities to revisit this issue and devise a less complex certification model.

Second, laboratories take a practical approach when implementing a system of monitors to assure data quality. Laboratories are more likely to find useful indicators that directly reflect the quality and accuracy of the information they generate, and are more likely to implement these in the laboratory. Such indicators as "proficiency testing results" and "quality control samples" give a direct look at the accuracy of the measurement made in the laboratory and hence are considered of more utility to the laboratory. Indicators such as "patient satisfaction surveys", which provide an oblique look at the total quality of laboratory services, are not considered as highly as useful. Indicators which are found more useful are also more likely to be used. This indicates a definition of quality that is tied to the number generated rather than to the total service provided.

Third, this type of assessment carries over into how the facility selects a reference facility, and how it views the definition of quality as it applies to the laboratory. The laboratories attempt to apply the most objective measures related to data quality, as well as measurable service standards such as turnaround times. This is consistent with broader trends in the profession, such as requirements that the performance of a new method be compared to objective reference specifications in order to be fit for publication (Fraser and Petersen, 1999).

Fourth, cost is a factor in how laboratories decide which tests to offer and which laboratory to use. However, this appears to be a minor reason for test choice for most laboratories. Managed care, despite a relatively small market penetration into Arkansas, does play a significant role in deciding where tests are performed. Almost a third of all laboratories, and nearly half of physician office laboratories, report that they “sometimes” or “often” are forced to send a specimen to an outside laboratory by a managed care contract despite running the test in-house. These findings raise troubling questions as to the impact on vulnerable populations, a matter of concern in this state.

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Acknowledgements

Peer Review

Steven J. Steindahl, Centers for Disease Control and Prevention
Sharon E. Granade, Centers for Disease Control and Prevention

Survey Logistics

Kathy Walker
Charles McGee
Victoria Green

Funding

CDC Laboratory Medicine Sentinel Monitoring Network Grant # U47/CCU617550-01