

## **Clinical Laboratory Personnel Employment Patterns: Hiring Practices and Quality Issues**

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**Abstract:** The state of Minnesota is in the forefront of managed care--approximately three-quarters of its residents are enrolled in this kind of provider system. The following report is concerned with a 25-year longitudinal study of employment patterns among laboratory personnel in the five-county Minneapolis-St.Paul area, which includes approximately 2.2 million persons, and almost 50% of the population of the state.

In 1970 there were over 10,000 hospital beds in 30 hospitals in the Twin Cities area. Also included among major employers of laboratorians were 2 blood banks and 4 clinic and reference laboratories. Altogether they employed approximately 1300 persons. In 1980 there were still 10,000 hospital beds, among 29 hospitals. Blood banks included 2 and clinics and reference labs included 6. During that decade, numbers of laboratory personnel almost doubled to 2500.

The impact of Prospective Payment and DRGs (1983) profoundly affected employing institutions and personnel in the 1980s. By 1990 hospital mergers and closures had reduced bed numbers to 7500, among 20 hospitals. There were 2 blood banks, and 9 clinics, reference labs, and HMOs, including 3 new reference laboratories. Total laboratory personnel employed were 2600.

By 1995 bed numbers were reduced to approximately 7000 among 18 hospitals. Again, there were 2 blood banks and 8 "other" employers. Total numbers of laboratory personnel employed were 2900.

We have seen a trend in hospital mergers and closures; since 1980, 10 major hospitals have closed or converted to a different kind of facility. There have been only two small suburban hospitals built in the last decade. Laboratory personnel almost doubled between 1970 and 1980. However, despite a decrease in hospitals, laboratory personnel numbers increased slowly, after 1980, largely due to new employing organizations, primarily independent commercial laboratories, as well as an increase in volume of testing.

Current (1995) employment trends include the following:

- baccalaureate-level medical technologists (clinical laboratory scientists) continue to be hired primarily in hospitals--regardless of size, where they make up 59% of all personnel. They comprise one-half of all laboratory employees.
- medical laboratory technicians are being hired mainly in HMOs and clinics. One of every five laboratorians is an MLT.

- cytotechnologists are being hired largely in medium-sized hospitals and independent laboratories, while histologic technicians/technologists are found mainly in medium-sized hospitals.

Personnel and issues of quality were addressed in the following retrospective study:

- A large HMO consisting of 1 central laboratory and 19 satellite laboratories was evaluated for error rates. In an eight-month study, all 20 laboratories had fewer than 1% laboratory errors among total tests. The central laboratory had the lowest error rate, averaging 0.05%. However, some satellite laboratories had somewhat larger error rates. Using common statistical analyses, there was no relationship between error rates and numbers of tests, workload, or kinds (levels) of personnel employed.

The connection between personnel and competency can be evaluated directly and indirectly. Direct methods include observation, establishing a relationship between proficiency test results and the personnel performing those tests, and establishing the relationship between laboratory error rates and kinds of personnel employed. One indirect method includes hiring practices, using the premise that employers hire those personnel whom they believe appropriate to their laboratory settings.

This paper describes both measurements--direct, in correlating laboratory errors and personnel in a major HMO consisting of 19 satellite laboratories and a central laboratory in the Twin Cities, and indirect, in a 25-year study of hiring practices in major laboratories in the Minneapolis-St. Paul area.

### **Hiring Patterns**

Since 1970, and at 5-year intervals, we have surveyed employers of laboratory personnel in this five-county geographic area of 2.2 million residents. In this paper, laboratory settings and personnel numbers from January of 1970, 1980, 1990, and 1995 are compared (Figure 1).

Figure 1 shows the growth in numbers of laboratory personnel between 1970 and 1995. In 1970 there were 30 hospitals, 2 blood banks, and 4 clinic/HMO/reference laboratories in this area. Altogether they employed 1300 laboratory personnel. In one decade, numbers of personnel almost doubled, to 2500 in 1980; by 1990 there were 2600 laboratorians. In 1995 there were 18 hospitals, 2 blood banks, 3 reference labs and 5 clinics/HMOs, employing 2900 laboratorians. Between 1980 and 1995, 10 hospitals in the Twin Cities closed or were converted to another kind of facility, e.g., psychiatric or rehabilitation. Two small suburban hospitals were built in the 1980s. Despite the loss of traditional hospitals and their laboratories, numbers of laboratory employees increased--partly due to numbers of personnel in reference (independent) laboratories. Between 1990 and 1995, numbers of lab personnel increased almost three-fold in three independent laboratories.

Tables 1 - 3 provide a synopsis of these data. Table 1 shows a comparison between years 1990 and 1995 of the numbers and kinds of laboratory personnel by employing institutions. It can be seen that hospitals of all sizes continue to employ, primarily,

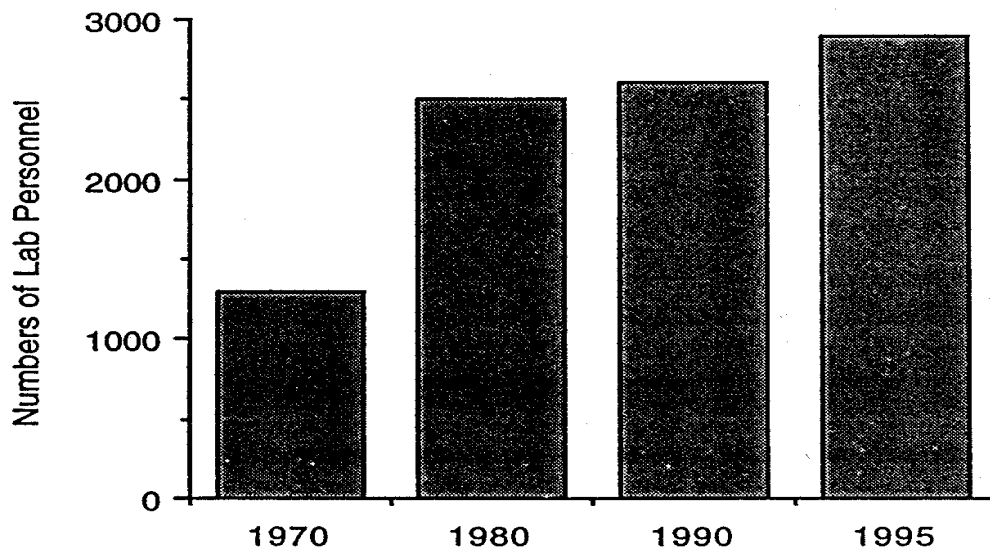


Figure 1. Total numbers of Twin Cities laboratory personnel from 1970 - 1995.

baccalaureate-level technologists, who comprised 59% of laboratorians employed in the 18 hospitals surveyed. In contrast medical laboratory technicians made up 65% of the laboratory personnel in clinics and HMOs, and 22% of total laboratorians employed in all institutions.

Most cytotechnologists (85 total) and histologic technicians (84) were employed in large and medium hospitals. Most phlebotomists and "others" were located in medium-sized hospitals and independent laboratories.

Table 2 shows categories and numbers of personnel by full-time or part-time status. Overall, full-time laboratorians outnumbered part-time personnel 3:1.

Table 3 provides information on hospital closures and openings since 1980. Here 10 hospitals closures, or conversions, released a total of 387 laboratorians (64% of whom were technologists) into the work force,

while two new small hospitals brought 66 employees into the work force. The net loss (from closures over openings) was 321 laboratory personnel. Despite these closures, numbers of personnel increased to 2914 in 1995.

What might have caused this increase? One reason is increased volume of testing. As part of the survey, laboratory administrators were asked to report whether their laboratories had experienced increased or decreased test volume between 1990 and 1995. All 4 large hospitals, 6 of the 10 medium hospitals, and 3 of 4 small hospitals reported an increase in volume of testing during that period.

Both blood banks also showed increased testing; 4 of 5 clinics/HMOs had an increase; and 2 of 3 independents also showed an increase. (Three medium hospitals reported a decrease, 1 hospital had no change, and 3 institutions did not provide data.) Thus,

INSTITUTIONS  
SURVEYEDTWIN CITIES-MINNEAPOLIS-ST. PAUL  
NUMBERS OF LABORATORY PERSONNEL

	CLS/MT		CLT/MT		Cyto and Histo Techs		Others, inc. Phlebotomy		Total	
	1990	1995	1990	1995	1990	1995	1990	1995	1990	1995
<b>Large Hospitals (4)</b> Abbott-NW, UMHC, VAMC, Riverside MMC>(*1990 only)	532	553	112	120	37	50	129	97	810	820
<b>Medium Hospitals (10)</b> North, United, Methodist, Hennepin, Ramsey, Fairview-So., St. Joseph's, Mercy, Unity, Midway	552	512	137	140	88	91	193	278	970	1021
<b>Small Hospitals (4)</b> St. Paul Children's, Mpls. Children's, St. John's NE, Fairview Ridges, Divine Redeemer* (*1990 only)	111	110	30	21	6	6	27	25	174	162
<b>Total (18)</b>	1195	1175	279	281	131	147	349	400	1954	2003
<b>Blood Banks (2)</b>	82	65	54	75	0	0	1	39	137	179
<b>Independents (3)</b>	82	148	15	34	10	22	17	155	124	359
<b>HMOs/Clinics (5)</b>	68	76	244	242	0	0	30	55	342	373
<b>Grand Total 30 (1990) 28 (1995)</b>	1427	1464	592	632	141	169	397	649	2557	2914

Table 1. Comparison of the numbers and types of laboratory personnel by employer, 1990 vs. 1995.

	<b>Full-Time</b>	<b>%</b>	<b>Part-Time</b>	<b>%</b>	<b>Total</b>	<b>% of all Personnel</b>
<b>CLS/MT</b>	1155	79%	309	21%	1464	50%
<b>CLT/MLT</b>	464	73%	168	27%	632	22%
<b>Cytotechs</b>	72	85%	13	15%	85	3%
<b>Histotechs</b>	69	82%	15	18%	84	3%
<b>Other</b>	265	69%	117	31%	382	13%
<b>Phlebotomists</b>	175	66%	92	34%	267	9%
<b>Total</b>	2200	75%	714	25%	2914	100%

Table 2. Category and Numbers of Personnel in 1995

summary data revealed, that at least 21 institutions (75%) had an increase in numbers of tests performed between 1990 and 1995. This probably accounted for the need for additional personnel.

Finally, in relating kinds of categories of personnel employed by different kinds of institutions, it seems logical that hospitals with acute care patients would need more CLS laboratorians trained at the baccalaureate level. On the other hand, HMOs and clinics, which see a clientele that is not as ill, could employ more two-year trained laboratory technicians, rather than four-year technologists.

### Laboratory Error Rates and Personnel

A second study involved the retrospective analysis of laboratory error rates in 1 central laboratory and 19 satellite (clinic) laboratories of an HMO in the Twin Cities area. This HMO was established in 1956 and currently enrolls 241,440 members.

Errors were documented in 13 general categories (Figure 2). Figure 2 also includes

examples of various errors, within 3 of the categories defined.

For each of the 20 laboratories, error rates for each of 8 consecutive months were determined and then averaged. They ranged from 0.05% (central laboratory) to 0.45% (Figure 3). Correlation analyses (e.g., Spearman and Pearson) were performed using 6 variables: error rate, education (ratio of MLTs to MTs) CAP workload, test volume, workload/test (W-T) and workload/CLS + CLT (W-M). Results are seen in Table 4. Multi-regression of error rates with other variables showed that no variable met the 0.1500 significance level for this model.

Although it might be tempting to conclude that error rates were not correlated with kinds of personnel employed (4-year CLS/MT or 2-year MLT personnel), one should not do so. Firstly, all error rates were low, less than 0.5%. Secondly, this laboratory system is well established and uniform in its function. For example, all satellite laboratories perform the same

Table 3

**CHANGES IN MAJOR CLINICAL LABORATORIES IN THE TWIN CITIES: 1980 - 1995**

**Numbers of Hospital Lab Personnel Employed in 1980 Whose Institution has Closed or  
Converted to a Psychiatric, Rehabilitation or Long-Term Care Facility**

Hospital	Year Closed/ Converted	Bed Size At Closing	Lab Personnel by Category at Closing				
			CLS/MT	CLT/MLT	Cyto/Histo	Others	Total
Riverview	1980	55	5	5	0	0	10
Golden Valley	1981	344	13	6	1	3	23
Eitel	1985	135	10	4	1	4	19
Lutheran Deaconess	1986	216	20	8	1	3	32
Samaritan	1987	78	21	7	2	5	35
Mounds Park	1987	205	26	3	0	0	29
Bethesda	1987	298	43	5	4	9	61
St. John's-St. Paul	1987	346	49	10	2	2	63
Metropolitan Med. Ctr.	1991	668	55	37	10	0	102
Divine Redeemer	1992	130	5	5	1	2	13
<b>Total Loss of Beds/Personnel</b>		<b>-2475</b>	<b>-247</b>	<b>-90</b>	<b>-22</b>	<b>-28</b>	<b>-387</b>

**Numbers of Laboratory Personnel Employed in Hospitals That Opened After 1980**

Year Institution Opened	Bed Size	MT/CLS	MLT/CLT	Cyto/Histo	Others	Total
		1995	1995	1995	1995	1995
St. John's NE (1985)	169	24	4	2	12	42
Fairview-Ridges (1984)	150	19	4	0	1	24
<b>Net Loss (1995)</b>	<b>Beds -2156</b>	<b>MT/CLS -204</b>	<b>MLT/CLT -82</b>	<b>Cyto/Histo -20</b>	<b>Others -15</b>	<b>Total -321</b>

Table 3. Changes in Major Clinical Laboratories in the Twin Cities: 1980-1995

### Categories of Errors

1. Errors in data/result entry - RE errors
2. Errors in data/result entry - MEM errors
3. Errors in data/result entry - CEM errors
4. Errors in data/result entry - DRWP errors
5. Misuse of code/test
6. Specimen processed incorrectly by lab
7. Missed order on MSR, unable to perform test
8. Mislabeled or unlabeled specimen - lab
9. Test ordered but not performed
10. Non lab processing errors
11. QC errors
12. Testing errors (technical)
13. PHON1 not documented

#### Example 1: Specimen

##### Processed Incorrectly by Lab

- Specimen not frozen
- Wrong tube drawn
- Wrong test ordered from reference lab
- Patient given incorrect container
- Wrong chart number entered into EKG machine
- Wrong culture plates set up
- Tube sent back to clinic by Central Lab
- Wrong amount of Trutol given for GTT

#### Example 2: Testing Errors (Technical)

- Reported morphology does not agree with CBC parameters
- Incorrect calculation on manual counts
- 200 cell diff not done with elevated monos, eos, or basos
- >50,000 WBC not sent to RI for Hemocue
- Procedure not followed for followup of abnormal values
- Prelim and final reports do not agree (Malarial smear, gram stain, HCON, etc.)
- Testing not completely documented

#### Example 3: QC Errors

- QC failure on any control. Appropriate troubleshooting procedures are not performed and documented before patient results are reported
- QC not appropriately documented (including date, test, results, tech, and computer input).
- Holdover out of range. No followup performed.

Figure 2. Categories and Examples of Errors Documented Within the Laboratory

procedures (Figure 4) using the same instruments. While MLTs were the predominant personnel in these satellite laboratories, each laboratory was headed by a baccalaureate-level technologist.

The central laboratory employed more technologists than technicians and performed the more complex testing for this HMO. It

also had the greatest volume of testing.

Finally, all 20 laboratories performed well and below the QC established limit of an overall 1% or less error rate. Whether the different kinds of personnel performing the testing could be correlated to laboratory errors could not be established.

In summary, using employment patterns

**Variables**

## Personnel

Clinic	Cummulative %Errors /8 months	#MLT (2yr)	#MT (4yr)	CAP Workload/unit s/month	Total Tests/month
1	0.45	3	0.4	10,400	1,060
2	0.44	11	1	35,840	3,700
3	0.42	4	0.6	13,040	1,300
4	0.40	3	0.6	11,425	1,270
5	0.39	7	1	35,050	3,510
6	0.38	9	0.5	25,280	2,660
7	0.35	3	0.4	6,870	660
8	0.32	5	0.5	13,240	1,480
9	0.30	6	0.85	27,400	2,770
10	0.22	3	0.4	11,200	1,250
11	0.19	7	0.7	26,670	3,100
12	0.17	8	0.7	31,200	3,290
13	0.16	3	0.3	6,910	680
14	0.16	5	0.7	18,000	1,780
15	0.15	6	1	39,800	4,150
16	0.13	3	0.5	10,600	940
17	0.13	8	1	34,050	4,260
18	0.10	3	0.3	8,170	860
19	0.10	12	1	60,250	6,970
20(Cent)	0.05	11	14	149,160	56,000

Figure 3. Comparison of errors rates of 20 laboratories over an 8 month period using 6 variables



**Correlation analysis using Spearman without CENTRAL Lab**  
**Correlation Analysis**

	<u>N</u>	<u>Mean</u>	<u>Std Dev</u>	<u>Median</u>	<u>Minimum</u>	<u>Maximum</u>
Error	19	0.26105	0.12692	0.22000	0.10000	0.45000
Ratio	19	0.89075	0.02786	0.88235	0.83333	0.94737
Workload	19	22389	14423	18000	6870	60250
Tests	19	2405	1652	1780	660.00000	6970
W-T	19	9.55714	0.75296	9.59036	7.99296	11.27660
W-M	19	3301	910.82713	3158	2021	5686

**Spearman Correlation Coefficients / Prob > IRI under Ho: Rho=0 / N = 19**

	<u>ERROR</u>	<u>RATIO</u>	<u>WORKLOAD</u>	<u>TESTS</u>	<u>W-T</u>	<u>W-M</u>
<b>ERROR</b>	1.00000 0.0	-0.16960 0.4876	-0.10716 0.6624	-0.13175 0.5908	0.19851 0.4153	-0.24506 0.3119
<b>RATIO</b>	-0.16960 0.4876	1.00000 0.0	0.14870 0.5435	0.18830 0.4401	-0.38364 0.1049	-0.22437 0.3558
<b>WORKLOAD</b>	-0.10716 0.6624	0.14870 0.5435	1.00000 0.0	0.98596 0.0001	-0.42105 0.0726	0.75789 0.0002
<b>TESTS</b>	-0.13175 0.5908	0.18830 0.4401	0.98596 0.0001	1.00000 0.0	-0.50877 0.0261	0.75789 0.0002
<b>W-T</b>	0.19851 0.4153	-0.38364 0.1049	-0.42105 0.0726	-0.50877 0.0261	1.00000 0.0	-0.38070 0.1078
<b>W-M</b>	-0.24506 0.3119	-0.22437 0.3558	0.75789 0.0002	0.75789 0.0002	-0.38070 0.1078	1.00000 0.0

**Correlation analysis using Spearman with CENTRAL Lab**  
**Correlation Analysis**

	<u>N</u>	<u>Mean</u>	<u>Std Dev</u>	<u>Median</u>	<u>Minimum</u>	<u>Maximum</u>
Error	20	0.25050	0.13225	0.20500	0.05000	0.45000
Ratio	20	0.86821	0.10437	0.88235	0.44000	0.94737
Workload	20	28728	31632	21640	6870	149160
Tests	20	5085	12092	2220	660.00000	56000
W-T	20	9.21246	1.70680	9.54706	2.66357	11.27660
W-M	20	3435	1068	3166	2021	5966

**Spearman Correlation Coefficients / Prob > IRI under Ho: Rho=0 / N = 20**

	<u>ERROR</u>	<u>RATIO</u>	<u>WORKLOAD</u>	<u>TESTS</u>	<u>W-T</u>	<u>W-M</u>
<b>ERROR</b>	1.00000 0.0	-0.00189 0.9937	-0.23485 0.3189	-0.25593 0.2761	0.31314 0.1788	-0.35303 0.1268
<b>RATIO</b>	-0.00189 0.9937	1.00000 0.0	-0.01583 0.9472	0.01809 0.9397	-0.18545 0.4338	-0.33547 0.1482
<b>WORKLOAD</b>	-0.23485 0.3189	-0.01583 0.9472	1.00000 0.0	0.98797 0.0001	-0.50376 0.0235	0.79248 0.0001
<b>TESTS</b>	-0.25593 0.2761	0.01809 0.9397	0.98797 0.0001	1.00000 0.0	-0.57895 0.0075	0.79248 0.0001
<b>W-T</b>	0.31314 0.1788	-0.18545 0.4338	-0.50376 0.0235	-0.57895 0.0075	1.00000 0.0	-0.46917 0.0369
<b>W-M</b>	-0.35303 0.1268	-0.33547 0.1482	0.79248 0.0001	0.79248 0.0001	-0.46917 0.0369	1.00000 0.0

Table 4. Results of Correlation Analyses (Spearman and Pearson) using 6 variables.

Laboratory Procedures

Bleeding Time	Mono Test
Blood Collection (Phlebotomy)	Nasal Smear
Body Fluids, Spinal Fluid, Synovial Fluid	Parasite Identification Microscopic
CDC	Arthropods
Crystals - Synovial Fluid	Pinworms
Differentials, Morphology & Platelet Estimate, Wright Stain	Platelet Count - Manual/Platelet Estimate
Direct Gram Stain	Pregnancy Test - Urine or Serum
ECG	RBC Count - Manual
Eosinophil Count	Reducing Substances
Glucose	Reticulocyte Count
Glucose Tolerance Test, 2 hour P.C.	Sedimentation Rate (ESR)
Gram Stain Rapid Method	Semen Analysis, Post Vasectomy, Post Coital
Hematocrit	Stool for PMNs, Eosinophils, or Yeast
Hemocult	Strep Screen Group A
Icotest	Urinalysis
Ketones - Serum	Urine Crystals
KOH	WBC Count - Manual
Malaria Smear	Wet preps

Figure 4. List of Laboratory Procedures Performed in all Satellite Laboratories

to demonstrate personnel requirements for different kinds of laboratory settings, this study showed that more technologists were employed in hospitals, while more technicians were employed in HMOs and clinics. These patterns probably reflected severity of illness of patient clientele and kinds of testing needed, e.g., simple versus complex. Moreover, despite the closure of 10 hospitals in this geographic area, numbers

of laboratory personnel increased slightly during the same period. In correlating laboratory error rates with five other variables, no definitive associations were established.

Thus, further studies need to be performed in order to link performance of laboratory testing with data concerning staff competency.

## **A Prospective Study of Career Patterns of Medical Technologists: Preparation and Entry-Level Practice**

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**Abstract:** In 1994, the American Society of Clinical Pathologists - Board of Registry (ASCP-BOR) began a 10-year prospective longitudinal study of the career patterns of medical technologists. A sample of individuals who took the August 1993 Medical Technologist certification examination was selected to be surveyed annually from 1994 to 2003. The study design includes the annual collection of demographic data such as employment status and personal status. In addition, topics have been identified for more in-depth study on a rotational basis each year. These include specific responsibilities, job satisfaction, professional activities, non-salary benefits, career commitment, and efficacy outcome.

Job responsibilities and educational preparation were focus areas for Year One of the study. The ASCP-BOR mailed 2,002 surveys to individuals who took the August 1993 medical technologist examination. 1,156 usable surveys, a 57.7% rate of return, were assessed with respect to first-year job responsibilities and quality of educational preparation to perform each job responsibility. Overall, respondents rated educational preparation as excellent for areas of responsibility performed with greatest frequency.

This longitudinal national study provides an opportunity to evaluate factors which influence the career patterns of medical technologists. The survey can serve as a vehicle to collect data and information on the evolution of skills and responsibilities of medical technologists as they adjust to the changing environment in health care delivery.

In 1994, the American Society of Clinical Pathologists - Board of Registry (ASCP-BOR) began a 10-year prospective longitudinal study to develop description information on the career patterns of medical technologists. A sample of individuals who took the August 1993 Medical Technologist certification examination was selected to be surveyed annually from 1994 to 2003.

### **Study Design**

The study design includes the annual collection of demographic data such as employment status, job title, department, institution type, institution setting, salary,

advanced education, and marital status. In addition, topics have been identified for more in-depth study on a rotational basis each year (Table 1). These include specific responsibilities, job satisfaction, professional activities, non-salary benefits, career commitment, and efficacy outcome.

- **Specific responsibilities** include technical skills, knowledge base, judgment and analytical decision making, teaching and training, supervisory management and administration, and communications.

Demographics	Specific Responsibilities	Job Satisfaction	Professional Activities	NonSalary Benefits	Career Commitment	Efficacy Outcome
1993	1993	1993				
1994			1994	1994	1994	
1995	1995	1995				
1996					1996	1996
1997	1997		1997	1997		
1998		1998			1998	
1999	1999		1999			1999
2000		2000		2000	2000	
2001	2001		2001			
2002		2002			2002	2002

Table 1. Matrix of Survey Topics by Year of Survey

- **Job satisfaction** covers personal fulfillment, relationship with coworkers and supervisors, benefits, job security, monetary rewards, recognition, and promotional opportunities.<sup>1</sup>
- **Professional activities** include professional organizational memberships, professional organizational activities, continuing education activities, research activities, and community service.
- **Non-salary** benefits include vacation, sick leave, pension, child care, educational support, and insurance.
- **Career commitment** is designed to gauge the individual's long term commitment to the "profession" as distinguished from one's satisfaction or commitment to a single organization and the expected utility of one's present job for future attainment of valued career outcomes.<sup>2</sup>
- **Efficacy outcome** is the ability of the individual or the department in which they work to accomplish the tasks to be done.<sup>3</sup> This includes scales on personal efficacy beliefs, personal outcome expectancy, collective efficacy beliefs, and collective outcome expectancy.

#### Study Population

The ASCP-BOR mailed 2,002 surveys to individuals who took the August 1993

medical technologist examination. A total of 1,156 usable surveys were returned, yielding a 57.7% response rate. (Table 2)

### **Frequency of Tasks Performed**

Specific responsibilities on the job and educational preparation for the job were focus areas for Year One of the study. The job responsibilities consisted of a 30-item list of tasks divided into six broad categories: technical skills; knowledge base; judgment and analytical decision making; teaching and training; supervision, management, and administration; and communication. The responses were assessed with respect to frequency with which respondents indicated they performed certain tasks. Table 3 lists the tasks most frequently performed. Table 4 lists the tasks least frequently performed.

### **Preparation for Entry Level Practice**

Respondents were also asked to rate the quality of their educational preparation to perform each job task. Overall, respondents rated educational preparation as excellent for areas of responsibility performed with greatest frequency (Figure 1).

### **Comment**

The responses to an annual survey of a cohort of medical technologists conducted

over 10 years will form the basis for the developing a series of profiles on the careers of medical technologists. The profiles will include job duties and responsibilities, work patterns, promotion and retention. In addition, the study provides the opportunity to assess the relationship between personal and professional development and other variables such as job satisfaction, career commitment and efficacy outcomes.

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1993 Examinees	Training Route*	Experience Route(s)**	Total
Sample	1,797	205	2,002
Responses	1,027	129	1,156 (57.7%)

\* Baccalaureate degree and completion of NAACLS accredited Medical Technologist program

\*\*Baccalaureate degree and 3-5 years clinical laboratory experience

Table 2. Sample Population and Response Rates: Year 1

1. Maintain confidentiality of test results
2. Perform routine laboratory tests
3. Recognize normal and abnormal values
4. Perform preventive maintenance
5. Correlate abnormal values with disease status
6. Recognize problem in quality control results
7. Perform quality assurance activities
8. Perform specialized laboratory tests
9. Communicate technical information to medical and laboratory persons
10. Troubleshoot laboratory instruments

Table 3. Most Frequently Performed First-Year Tasks

1. Work with legislative activities
2. Prepare and present lectures
3. Supervise laboratory projects
4. Purchase reagents
5. Evaluate educational programs
6. Supervise laboratory personnel
7. Establish technical procedures
8. Select new instruments and reagents
9. Perform utilization studies
10. Develop manuals, etc.

Table 4. Least Frequently Performed First-Year Tasks

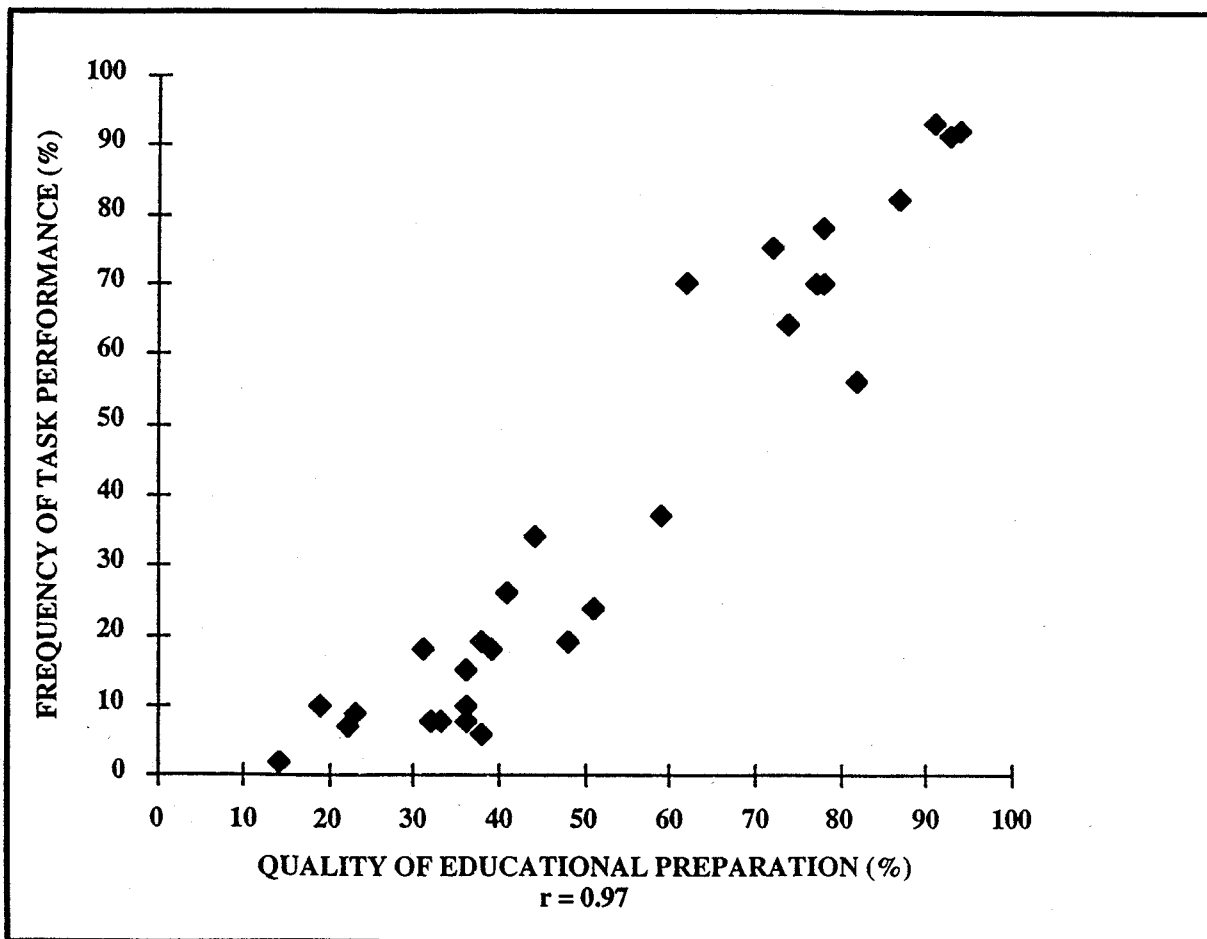


Figure 1. Educational Preparation vs Entry-Level Practice

## **Back to Basics: In-depth Interviews and Focus Groups as Methods for Assessing Technical Competence**

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San Diego, California**

**Abstract:** Quantitative research on laboratory personnel issues requires a solid footing in theory and a basic understanding of the issues related to the empirical question. Through a cooperative agreement with CDC, the Graduate School of Public Health at San Diego State University is assessing the relationship of personnel qualifications and laboratory performance. We have used in-depth interviews and have adapted a method of task assessment as steps in our efforts to understand technical competence.

The task analysis project seeks to understand the knowledge, skills, abilities and other traits (KSAOs) that are essential to perform a sample laboratory test, in this case Enzyme Immunoassay (EIA) testing for Human Immunodeficiency Virus (HIV) antibody, in a competent versus superior manner. A standard industrial task analysis method was modified for use. Ten subject matter experts rated each of 60 selected tasks for its frequency, criticality, and difficulty. These experts then met in a facilitated focus group to identify the mental and physical behaviors and KSAOs for the five top-rated (most important) tasks. Eight KSAOs were common to all of the five top-rated tasks. The challenges of understanding personnel competence in the context of a complex technology-dependent industry are discussed. KSAOs believed essential for superior performance were also identified. This information was used in developing an on-site observation checklist to be used in observing performance of HIV antibody testing.

Since competence assessment (C/A) under CLIA'88 is a timely and relevant issue, we used in-depth telephone interviews of laboratory supervisors and technologists responsible for implementing this aspect of laboratory quality assurance. The primary intent of the in-depth interviews was to clarify and refine research questions for further study and to better understand, from a broad cross-section of 20 laboratory supervisors, other relevant aspects of personnel competence and quality management. Results allow a preliminary picture of C/A implementation status and issues in the practice community. Content analysis of selected questions provides a method of identifying common themes and an understanding of the variety of ways that C/A is used to comply with CLIA'88 and to improve management's confidence in their personnel.

### **Introduction**

This report describes methods used to conduct in-depth interviews, task analysis and focus groups.

### **The CLIA Question: How are personnel qualifications related to performance?**

It is important to understand that the long range goal of this project is to develop a clearer understanding of the relationship of



the laboratory personnel, the qualifications, and how those qualifications relate to the performance of clinical laboratories. Of particular interest are the personnel qualifications that were established as a part of CLIA'88 regulations.

### **Literature Review**

For initiating this project, an extensive literature search to examine clinical laboratory science/medical technologists' personnel qualifications, competence, and other aspects of human performance in clinical laboratories was undertaken. Unfortunately, most of the useful literature seems to end in the mid-1980s, perhaps coincident with the decline of many university-based medical technology/clinical laboratory science programs. All in all, there is a dearth of specific information about technical or other competencies needed for performance. While many studies have been undertaken, they tend to focus primarily on clinical laboratory science students and their performance. Another pattern that emerged from the literature was that while many initial investigations were conducted, potentially productive lines of research were not followed up. One of the other deficiencies found in the literature was a lack of any overall theoretical framework or conceptual models to guide research efforts in this area. In an attempt to improve our understanding of the fundamentals, we also searched non-health care literature from the human resources management, industrial psychology, and ergonomics. We identified methodological approaches and general conceptual frameworks that could be useful to conduct our research. One of the useful frameworks is the mental workload model drawn from the industrial engineering, ergonomics and industrial psychology

literature.<sup>1</sup>

Task analysis and the focus groups are methods that were used to determine the most important tasks and to identify the physical and mental behaviors as well as knowledge, skills and other abilities (KSAOs) required to competently perform the highly complex HIV enzyme immunoassay test.

There is no one single way to conduct a task analysis or a focus group in this or any other context.<sup>2,3</sup> Task analysis and focus group are ambiguous terms often applied to many types of analyses and used for many purposes. We did not develop either the task analysis or focus group methodology. We have adapted and used bits and pieces of various methods, combining them to achieve our ultimate goal: to determine if we can observe significant differences in laboratory personnel behavior that might explain variations or increase in the likelihood of error in the analytical performance of this particular laboratory test.

To initiate this project, we searched the literature to find commonly used task analysis methods that had been applied to clinical laboratory testing. We found no common or standard methods, although we did find several examples of analyses of tasks most commonly, surveys that were conducted to identify tasks of various levels of laboratory personnel. We also searched human resources management and organizational psychology literature for methodologies that might be useful. Several references were located and found useful, primarily from a text by Gael.<sup>2</sup>

### **Project Staff and Consultants**

Theory and good research ideas are only useful if they can be implemented effectively. We are very fortunate to have hired Ms.

1. Takes corrective action when equipment is not working.
2. Detects physiologically impossible or unreasonable results and troubleshoots.
3. Pipettes specimen or reagents appropriately and accurately.
4. Performs preventive maintenance on equipment as scheduled and accurately records all quality control, test identification, maintenance.
5. Visually looks at each specimen for hemolysis, precipitation, and quantity sufficient for testing; analyzes and makes judgments as to specimen acceptability.

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*The five tasks which received the highest TIV scores\* were considered the most important.*

\* The Task Importance Value (TIV) = Frequency + (Difficulty x Criticality) was calculated for each HIV EIA task by each Subject Matter Expert. A cumulative score was determined for each task.

Table 1. Most Important HIV EIA Tasks

Linda Christian, who, in addition to experience in medical technology, has experience as a medical technology educator and laboratory manager and quality improvement coordinator. She was well versed in developing job descriptions as well as periodic personnel performance appraisals, test construction and evaluation of skills needed for the laboratory. We were assisted by a human and organizational system consultant, Ms. Veronica Myers, MSBA, from the College of Business Administration at San Diego State University. In addition to teaching human resources, she has considerable experience in a large multi-institutional health care organization in human resources development. Working with a nonlaboratorian expert helped us clarify our objectives as well as select and refine the methodologies.

### **Overall Strategy**

The overall strategy undertaken consisted of three parts: First, relevant tasks in HIV EIA testing were identified. Second, the most important of these tasks were identified. Third, a list of knowledge, skills, abilities and other characteristics (KSAOs) of

testing personnel for competent performance of the most important tasks was generated.

### **Identify Important Tasks**

We identified from experience, review of EIA Kit inserts, previous laboratory on-site visits, previous focus group consensus, and previous laboratory written surveys, the relevant tasks involved in various methodologies of the HIV EIA test. Approximately 60 separate tasks were identified. They were categorized and may be seen in a 3-page task rating form which is included as Appendix A.

To validate our list of tasks and to identify the most important tasks in our task analysis, we recruited a panel of subject matter experts (SMEs), medical technologists who supervised HIV antibody testing in their laboratories. These SMEs were recruited at a state meeting of Clinical Laboratory Management Association, in addition to contacting laboratory supervisors who had previously participated in other focus groups. We used Likert-type rating scales for each of the 60 tasks. After they agreed to participate, rating forms were sent to 10 SMEs. Eight SMEs reviewed our list of tasks and rated each of the tasks as to its

frequency of performance, the difficulty of the task and how critical the task is in the context of the total testing process. We also asked our SMEs to add any task that we had not included, as well as tasks outside of the direct testing process that they regarded as important to the performance of this test (dilutors, specimen handling, reporting, etc.). The task rating forms were returned by mail. We calculated a Task Importance Value for each task rated by each SME using the following formula: Task Importance Value = Frequency + (Difficulty x Criticality). We then calculated a cumulative score for each task and rank ordered the tasks. The top-rated HIV EIA tasks are included as Table 1.

### **The Focus Group with Subject Matter Experts**

We convened our focus group meeting of nine SMEs in the late afternoon after working hours, starting with a meal and refreshments in order to create a collegial atmosphere in which to conduct our group work. The SME focus group included first-line supervisors from a broad spectrum of HIV testing facilities including a public health laboratory, hospital laboratories, a blood bank laboratory, independent laboratories, and a plasma processing facility. Our goal was to thoroughly analyze as many HIV EIA tasks as possible in the given amount of time. Ms. Myers, our human resources management consultant, facilitated our focus group discussion. The focus group meeting began with the explanation of the goals of this focus group meeting and the long-range goals of our cooperative agreement and the CLIA'88 studies. We made it clear that there were no right or wrong answers and that everyone's opinion was highly valued.

The SMEs reached consensus on the five

most important tasks to analyze during the meeting from a longer list of top-rated tasks. Next Ms. Myers wrote on a flip chart the highest-rated task, which was "Take corrective action when equipment is not working." Physical and mental behaviors for that particular task were identified by the focus group using a nominal group technique to assure that all group members had an opportunity to contribute. Flipcharts were used to record behaviors and (KSAOs). Members were polled until unique behaviors could no longer be elicited from the panel. Table 2 lists the behaviors as well as KSAOs for a sample task.

Task analysis was completed on the remaining four most important tasks for a total of five highly-rated tasks. A list of KSAOs found to be common for all of the tasks we assessed is presented in Table 3.

It also became clear during the discussion that the KSAOs for superior performance might be somewhat different from those KSAOs seen in the performance of persons judged merely as competent. As the group process evolved, a list of KSAOs of superior performers was also produced. These are listed in Table 4.

The focus group lasted approximately 2.5 hours. Given the interest of the group, it might have lasted longer had it not been for a failed air conditioner on an unusually warm day. We found that the SMEs were generally interested, often enthusiastic, and willing to challenge each other and share ideas. All participated, some more vigorously than others. After the meeting, we compiled the findings of the focus group meeting and mailed these to the SMEs. We asked them to make any corrections and to provide any additional after-thoughts. We also asked them to evaluate the focus group process in order to facilitate any

TASKS	BEHAVIORS		KSAOS
H3	Physical	Mental	
<p><b>Takes corrective action when washing (and other) equipment is not working.</b></p> <p>e.g. gets equipment up and running or chooses alternate equipment</p>	<p><u>Observe</u></p> <ul style="list-style-type: none"> <li>- if water on tray</li> <li>- if water in tank</li> <li>- if plugged in</li> <li>- if dispensing correctly</li> <li>- if wash volume accurate (measure)</li> <li>- pressure</li> </ul> <p><u>Inspect</u></p> <ul style="list-style-type: none"> <li>- wash manifold</li> <li>  Seals</li> <li>  Connection Pressure</li> <li>- replace broken part</li> <li>- log (write) actions</li> </ul>	<ul style="list-style-type: none"> <li>- mental flowchart of what to expect</li> <li>- not use the instrument?</li> <li>- notify supervisor?</li> <li>- call for supervisor?</li> <li>- spare part?</li> <li>- call technical service?</li> </ul>	<p>Written/oral communication skills</p> <p>Legible writing</p> <p>Ability to read</p> <p>Ability to follow instructions</p> <p>Knowledge of processes</p> <p>Attention to detail</p> <p>Tolerate personal protective equipment (e.g. gloves)</p> <p>Initiative</p> <p>  “Awareness”</p> <p>  Recognize a problem or the possibility of a problem</p> <p>  Act</p> <p>  Not wait to be told</p> <p>  Take responsibility</p> <p>Decision-making</p> <p>Satisfied with each step of the process</p> <p>-----</p> <ul style="list-style-type: none"> <li>- trained on proper operation of equipment</li> <li>- analytical ability to judge</li> <li>- Know how to use/follow manual</li> <li>- find things</li> <li>- knowledge of testing process</li> <li>- eyesight sufficient to observe drops of water at two feet</li> <li>- unscrew with hand (tactile)</li> <li>- communicate verbally to supervisor or manufacturer and written (to document, logs)</li> </ul>

1. Written/oral communication skills
  - A. Legible writing
2. Ability to read
3. Ability to follow instructions
4. Knowledge of processes
5. Attention to detail
6. Tolerate personal protective equipment (e.g. gloves)
7. Initiative
  - A. "Awareness"
  - B. Recognize a problem or the possibility of a problem
  - C. Act
  - D. Not wait to be told
  - E. Take responsibility
8. Decision-making
  - A. Satisfied with each step of the process

Table 3. KSAOs Common to 5 Most Important Tasks

improvements in future groups that we might conduct.

### **Use of Task Analysis and Focus Group Results**

Now the use of the results of the task analysis can begin. In an employment setting, it would be possible to have pencil and paper tests, simulations or other types of performance evaluations to measure the KSAOs that we now know are needed for HIV EIA testing. Task-oriented screening tests could be used to identify competencies in selecting or retraining personnel. A rigorous competence assessment program could measure and assure that all personnel conducting the testing could demonstrate the KSAOs shown to be essential in competently performing HIV EIA tests.

In our research we are observing the process for HIV testing in 10 volunteer laboratories. Using an observation checklist and focusing on selected tasks, we are attempting to observe various KSAOs and

other behaviors identified as most important by our focus group. We do not yet have results on the usefulness of direct observation to assess selected "critical" behaviors and KSAOs of the personnel doing the testing.

A thoroughly conducted task analysis is resource intensive, particularly when a focus group is used to identify behaviors and KSAOs. The biggest cost is the staff time required to develop the tasks list and task rating form, tabulate the results of the ranking survey and rank importance of the tasks, and calculate the Task Importance Values. Hiring a facilitator to lead the group discussion process also adds an expense. We also provided food and a small honorarium for our SMEs.

In a laboratory with a menu of several hundred tests, it would be difficult to conduct a rigorous task analysis for even a fraction of the tests. An alternative strategy would be to identify representative tests, the most critical tests, and/or the most critical

- Recognition of own limitations
- Ability to detect problems and act to correct
- Possesses innate curiosity about “why?”
- Understands what is doing and the importance of accuracy
- Understands the impact of actions on outcome
- Pays attention to accuracy
- Appreciates the importance of the test to the care of the patient (care about the patient)
- Willing to help others
- Pays attention to detail
- Positive attitude
- Follows procedures step by step (e.g. doesn’t take shortcuts)
- Willing to make decisions and accept responsibility
- “Awareness” (not specifically defined - analogy given of flying the plane, not on autopilot)
- Possesses moral character, truthfulness, integrity (e.g. doesn’t cover up mistakes)
- Pride of workmanship - relates their job to the outcome of the patient
- Meticulous
- Consistency in work

All of these characteristics would result in high quality work, less rework, fewer mistakes.  
High quality performance leads to productivity (enhanced by experience)

Table 4. KSAOs of Superior Performers

processes. Rather than individual laboratories conducting task analyses, a coordinated effort might be supported by professional organizations, manufacturers, or other agencies with an interest in resolving specific task-skill questions. Appropriately conducted rigorous task analysis could help resolve issues related to categorizing testing methodologies as high complexity or moderate complexity tests as required by CLIA’88 regulations. It is important to place task analysis into context. No matter how many task analyses we complete, they deal only with the analytic process, only one aspect of a very complex system. Given the other requirements for managing quality, the extent to which resources could be used for this purpose would have to be determined.

### **In-Depth Interviews and Personnel Competence**

A third method used to develop our knowledge of personnel and performance was in-depth interviews. Competency assessment is required by CLIA’88 quality assurance regulations<sup>1</sup>. The issue of personnel competence lies at the heart of the issue of personnel qualification and performance. Unfortunately there is little literature on this topic.<sup>3-6</sup> We used these interviews to identify important issues related to personnel and performance, to understand the current status of competency assessment, and to determine the feasibility of further quantitative studies of this topic.

As exploratory research, a self-reporting mailed survey is not practical. The issue of timing is also important. The length of time involved to develop, pretest, and pilot test a

written, self-reporting mailed questionnaire was not practical. In-depth telephone interviews have the advantage of being relatively rapid, providing the interviewer with the ability to probe and develop a better understanding of responses. They also allow for open-ended questions, which do not constrain the respondent to a predetermined particular short list of responses. Telephone interviews provided an opportunity to explore a broad range of complex issues.

The expense of telephone interviews is a disadvantage. Exploratory surveys with open-ended questions require a skilled individual with knowledge of the subject matter to conduct the interviews. It is also essential that the interviewer remain objective and not be judgmental when receiving responses. Open-ended questions are also labor intensive to interpret and do not lend themselves to quantitation.

In attempting to understand competency assessment, we started with regulations which stipulate what competency assessment activities occur in laboratories. A primary interest was to understand how various laboratories defined competence and competency assessment. Methods used to assess competency, such as pencil and paper examinations, specimen analysis, direct observation, or retrospective analysis of work, worksheets and quality control records were of interest as well. The relationship of competency assessment and other quality assessment or quality improvement practices, not only in the laboratory, but throughout the organization was of interest. For example, in hospital laboratories: What was the connection between competency assessment and other Joint Commission-required activities such as QA/QI programs? We were also interested in the relationship between periodic

personnel appraisals and competency assessment. Were there rewards or merit pay connected with the findings of competency assessment? Were there punitive actions? In an era of cost containment, the cost of personnel resources devoted to competency assessment must be considered. We queried laboratories regarding their perceptions on the overall value or usefulness of competence assessment. Our interview recording form, which lists the questions used in the interview, is included as Appendix B.

### **Sample of Laboratories**

An objective of exploratory in-depth interviews is to obtain a representative rather than statistically valid sample. The objective was to incorporate the views and qualitatively describe the practices of a diverse set of laboratories. To ensure that we obtained interviews from this broad range, we stratified our sample into four categories to include physician office laboratories, blood banks, hospitals, and commercial reference laboratories. The initial contacts were made to organizations that were known to have considerable experience in competency assessment. The initial case study was conducted by a health administration graduate student, Ms. Jean Breheme, who is a laboratory manager in a multi-institutional laboratory system. This laboratory has spent considerable resources over the past several years implementing a rigorous C/A program. Baseline information from this case study helped provide a framework for the interviews. We also contacted several individuals who had published or presented educational sessions on C/A at professional meetings. Literature we found is provided in the references.<sup>4-8</sup> From these leaders we also asked for

contacts at other laboratories who they believed to be doing a thorough job of implementing C/A. In the communication literature, identifying additional sample members by another case is known as a "snowball technique". Such a snowball technique is efficient because it allows identification of laboratories that have spent considerable resources. It also speeds the sampling process by identifying contact individuals rather than having to make "cold calls" to laboratories. We called several other laboratories that had cooperated with us in other aspects of various research projects. While this method is efficient, it could lead to a nonrepresentative picture by including only the most well-developed C/A programs in the sample. To identify a more representative sample, we turned to the on-line electronic yellow pages. Using the CompuServe Business File, we randomly chose metropolitan areas outside of California and identified laboratories to call. While it was easy to find blood banks, clinic laboratories, and hospitals, finding physician offices and medical group practices with CLIA-certified laboratories proved somewhat more difficult, many non-productive cold calls were made. Identifying internal medicine specialists/group practices was the most productive method to identify small physician office laboratories.

We called approximately 35 medical groups and physician's offices to identify laboratories for five in-depth interviews. We scheduled times that were convenient for the person most familiar with competency assessment to be interviewed. On average, it took about three calls to arrange and complete the interviews. Telephone surveys are labor-intensive. Interviews took approximately 30 to 60 minutes to complete.

### **Conclusions on Competence Assessment**

We found a continuum of the formality in implementing C/A as required by CLIA '88. At one end of the continuum several laboratories had extensive, formal competency assessment programs that far exceeded the CLIA '88 requirements. At the other end of the spectrum were laboratories with virtually no C/A activities and demonstrating minimal compliance. Blood bank and hospital laboratories had the most formalized C/A programs. Competency assessment tended to focus on technical competence of the analytic phase of testing, documenting the ability to do testing, being able to follow manufacturer's and the laboratory's standard operating procedures. Productivity was also important. The other domain of personnel competence of equal or greater importance was the "professionalism" of personnel. Professionalism was the ability to trust individuals to follow through and do what would be expected in situations. Further analysis and reporting of these results is currently underway.

### **Acknowledgments**

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worked on the task analysis and focus group project.

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<u>Instructions</u> Task statements are grouped below under general categories. Read each task statement carefully and decide whether or not the task is part of the HIV EIA test as performed by your personnel. If it is not, place a (v) in the NA column. Write in any additional task statements you believe are appropriate to the category. Some tasks may be considered more important/significant to the test outcome than others. Therefore, consider the following factors involved in judging the importance/significance of these tasks: <b>Frequency - How frequently is this task performed related to other HIV EIA test tasks?</b> <b>Difficulty - How difficult is this task compared to other HIV EIA test tasks?</b> <b>Criticality - To what degree does incorrect performance of this task result in adverse consequences or results?</b>	NA (v)	<u>Frequency</u> 1=very <u>infrequent</u>  3=average  5=substantial	<u>Difficulty</u> 1=not difficult 2=below average 3=average 4=considerable 5=substantial	<u>Criticality</u> 1=not critical 2=below average 3=average 4=considerable 5=substantial
<b>A. EQUIPMENT</b>				
1. Performs preventive maintenance on equipment as scheduled.				
2. Checks temperatures of incubator, water bath.				
3. Takes corrective action if temperatures deviate from acceptable range.				
4. Aspirates liquid using aspirating equipment.				
5. Washes beads using washing equipment.				
6. Primes dispenser immediately prior to dispensing color development solution.				
7. Blanks spectrophotometer at appropriate wavelength.				
8. Determines absorbance of control and specimens.				
9.				
<b>B. SPECIMENS</b>				
1. Clarifies specimen when specimen is determined to contain precipitate.				
2. Stores specimens appropriately.				
3. Avoids multiple freeze-thaw of specimens.				
4. Mixes specimens adequately before sampling.				
5. Determines which specimens and controls need to be tested				
6. Appropriately makes dilutions when necessary.				
7. Determines which specimens need repeating, pulls them and stores appropriately.				
8. Identifies and prepares/stores those specimens for confirmatory testing.				
9.				
<b>C. SPECIMEN IDENTIFICATION</b>				
1. Labels tubes/trays/wells legibly and appropriately.				
2. Accurately identifies results of specimen/controls from instrument printout.				
<b>D. REAGENTS</b>				
1. Stores reagents appropriately				
2. Determines if reagents are acceptable for use (checks expiration, checks for visible signs of deterioration).				
3. Prepares reagents by reconstitution, measuring, pipetting.				

Frequency - How frequently is this task performed related to other HIV EIA test tasks? Difficulty - How difficult is this task compared to other HIV EIA test tasks? Criticality - To what degree does incorrect performance of this task results in adverse results?	consequences or	NA (v)	Frequency 1=very infrequent 3=average 5=substantial	Difficulty 1=not difficult 2=below average 3=average 4=considerable 5=substantial	Criticality 1=not critical 2=below average 3=average 4=considerable 5=substantial
<b>D. REAGENTS (CONT'D)</b>					
5. Makes sufficient color development solution for testing.					
<b>E. QUALITY CONTROL</b>					
1. Prepares and pipets blank tubes.					
2. Accurately records all quality control, test identification, maintenance.					
<b>F. PSYCHOMOTOR</b>					
1. Mixes reagents prior to use.					
2. Pipets specimen or reagents appropriately and accurately					
3. Mixes dilutions tubes/wells adequately.					
4. Adds beads carefully to appropriate wells.					
5. Accurately times the incubations periods.					
6. Swirls color development solution gently prior to use.					
7. Transfers beads to appropriately labeled tubes.					
8. Inspects trays for trapped air bubbles.					
<b>G. DECISION-MAKING</b>					
1. Visually looks at each specimen for hemolysis, precipitation, and quality sufficient for analyzes and makes judgements as to specimen acceptability	testing;				
2. Decides if specimen needs to be rejected.					
3. Determines validity of run by assessing quality control results.					
4. Determines validity of reagents by absorbance difference between positive and negative	controls.				
5. Determines whether additional tests are appropriate based on the results					
6. Evaluates results to determine if the result is an accurate automated reading or the result of an equipment malfunction, reagent problems, or protocol deviation, and takes appropriate corrective action.					
7. Detects physiologically impossible or unreasonable results and troubleshoots.					
<b>H. CORRECTIVE ACTION</b>					
1. Takes corrective action if trapped air bubbles detected in trays.					
2. Takes corrective action when aspirating equipment is not working.					
3. Takes corrective action when washing equipment is not working.					
4. Takes appropriate action if QC is not acceptable.					
5. Takes action when impossible or unreasonable results are obtained.					

<b>Frequency - How frequently is this task performed related to other HIV test tasks?</b> <b>Difficulty - How difficult is this task compared to other HIV test tasks?</b> <b>Criticality - To what degree does incorrect performance of this task results in adverse consequences or results?</b>	NA (v)	<u>Frequency</u> 1=very <u>inf</u> requent  3=average  5=substantial	<u>Difficulty</u> 1=not difficult 2=below average 3=average 4=considerable 5=substantial	<u>Criticality</u> 1=not critical 2=below average 3=average 4=considerable 5=substantial
<b>H. CORRECTIVE ACTION (CONT'D)</b>				
6.				
<b>I. CALCULATIONS</b>				
1. Correctly determines the cutoff value.				
2. Correctly compares the resulting absorbances to the cutoff and classifies each specimen as to negative or reactive.				
3. Correctly follows testing algorithm and determines which specimens are negative, reactive, repeatably reactive, need to be confirmed, reported.				
4.				
<b>J. RECORDKEEPING</b>				
1. Prepares load list/worksheet.				
2. Records absorbances.				
3. Correctly follows testing algorithm and reports acceptable results.				
4.				
<b>K. PROBLEM SOLVING</b>				
1. Recognizes problems and identifies the cause.				
2. Solves problems by implementing or suggesting satisfactory solutions.				
<b>L. COMMUNICATION</b>				
1. Demonstrates professional interpersonal communications with patients, laboratory personnel, physicians, or other healthcare professionals about results or other aspects of the test.				
2. Prepares and transmits written and oral reports clearly and accurately.				
3.				
<b>M. OTHER</b>				
1. Follows all steps of protocol/procedure during testing.				
2. Protects oneself and coworkers by following safety precautions and using appropriate personal protective equipment.				
3. Increases and improves professional knowledge and skills by attending/presenting inservice lectures, seminars.				
4. Maintains confidentiality of all results				

**APPENDIX B  
COMPETENCY ASSESSMENT QUESTIONS**

Date:

Contact person:

QUESTIONS	Laboratory Name/Address	Code
<b>DESCRIPTION OF LABORATORY</b>		
Location of Lab (city, state)		
What type of Laboratory? Hospital Reference Physician Office Lab (POL) Group Practice Lab (GPL) Blood Bank (BB)		
If hospital, # beds		
If GPL or POL, # doctors		
If GPL or POL, kinds of lab services offered		
# licensed testing personnel		
# unlicensed testing personnel		
By which agencies are you accredited or licensed? AABB, State lic, JCAHO, CAP, COLA, others:		
<b>HISTORY AND DEVELOPMENT</b>		
Do you have a written Policy/ Procedure for competency assessment?		
When was it written?		
When did you begin competency testing? Or are you in the planning stages?		
Do you have an error detection system in place to pinpoint areas where competence needs improvement?		
What corrective actions are instituted to assist employees when problems are identified?		
Do you have a mechanism for assessing the competence of consultants:		
<b>DEFINITION OF COMPETENCY</b>		
How do you interpret "competent staff" as mandated by CLIA?		
What is the best indicator of competency?		
What are other indicators of competency?		

<b>PROCEDURE DETAILS</b>	
How are competency areas chosen?	
How often is competency testing done?	
Will all tests performed be observed eventually?	
"Passing" score	
What is done with/for employees who do not obtain a passing score?	
How does the lab assure that an individual who had problems in performance is competent after appropriate training and technical assistance is completed?	
How does the lab evaluate personnel for consistency in slide review (i.e. ANA, parasitology, cytology, hematology)?	
<b>INTERRELATIONSHIPS (QA/QI, PERIODIC EMPLOYEE EVALUATION, OTHER)</b>	
Is competency assessment of individuals linked to performance evaluations?	
Is competency assessment program linked to QA or QI program?	
What other activities besides competency assessment are done to improve quality?	
<b>EVALUATION OF COMPETENCY ASSESSMENT</b>	
What is the best assessment method?	
May I have copies of your competency assessment P/P and assessment instruments?	
May I have a copy of a performance evaluation form?	
Have you evaluated your competency assessment plan? Changed anything?	
Have you estimated how costly the competency assessment program has been?	
What benefits do you see from having a competency assessment program?	
What are your plans for the future as you envision competency assessment?	

ASSESSMENT METHOD	
Direct observation of test performance by supervisor Checklist used? Which tests/procedures do you observe?	
Direct observation of test performance by peer Checklist used?	
Direct observation of instrument maintenance Checklist used?	
Technical staff to perform Proficiency testing samples with performance documented (wet)	
Internal blind testing samples with performance documented (wet)	
"Leftover" proficiency testing specimens with performance documented. (wet)	
Pencil/Paper quiz of knowledge of SOPs, policies, basic troubleshooting for problem situations. (dry)	
Problem solving exercises with documentation (e.g. BB)	
Performance deficiencies or Incident reports in employee's file	
Other competency assessment methods?	

## The Changing Structure of Work: Use of Work Teams

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**Abstract:** This session discussed the use of work teams. Whether we like it or not, teams are playing a major role in most work settings. This session discussed the development of self-directed teams, their training, integration, leadership, and evaluation. The very nature of the process-oriented work in clinical laboratories lends itself to using work teams. The claimed benefits of teams include more integration of skills; tapping of unknown member resources; more stimulation, energy, and emotional support; more sustained effort at team goals; greater member satisfaction; and higher motivation.

By definition, a work team is a cohesive unit of highly motivated, highly skilled and highly trained workers who supervise themselves with the encouragement and direction of a coach. Although the coach is usually a manager who is responsible for directing several teams, this person can be the team leader. During the early life of a team, the team leader is often picked by management; later, the team itself picks the team leader. The team leader is responsible for calling meetings, insuring that necessary paper work and critical data are completed and documented; however, he or she is not a supervisor and the team itself will work to resolve any conflicts. Members of the team enjoy the privileges of empowerment as well as challenges of continuous improvement. Quality can be assured by continuous feedback or using a team member as a quality control expert.

In establishing teams, several questions must be kept in mind: What will the organization look like one or two years from now? How can we meet competition and lead and manage our business as we continue to push for higher quality and productivity? In what ways will we need to reengineer and change our current processes, jobs and culture to support the future business of the laboratory? How can we meet the legal requirements for quality control when we are using teams?

The very nature of the process-oriented work in clinical laboratories lends itself to the use of work teams. Properly functioning work teams can increase productivity and reduce personnel costs. They also can be more responsive to organizational changes needed to meet customer needs than hierarchical organizations; i.e., where there is a first-line supervisor to which employees report and a second-level supervisor to which the first-line supervisor reports, etc. I will discuss the development of teams and

their training, integration, leadership, and evaluation. I am not recommending this approach and it is not for every clinical laboratory.

Whether we like it or not, teams are playing a major role in most work settings. They will play an even larger role in the future. As economic trends force companies to downsize and focus on speed and efficiency, there has been a fundamental shift in organizational structures. Many factors can be attributed to this change in



organizational design. These factors have pushed the evolution of organizational structures from a hierarchical design, with a manager, several supervisors, and employees reporting to the supervisors, to a matrix design of self-directed teams that report to the manager or to a management team. The first level supervisor does not exist. The manager serves as a coach to many teams and insures that they stay on track by meeting with each team once a week every one or two weeks.<sup>1</sup> One laboratory that has moved to a team approach is the Washington Hospital Center. This hospital laboratory has moved from 12 to 3 supervisors/managers for a staff of approximately 300 with substantial savings in personnel costs and increased operational efficiency.<sup>2</sup> Also, SmithKline Beecham is using a team approach in its many laboratories; it uses a network of local, regional and national quality control experts to help insure that quality is maintained.

Quality control may be a critical issue in self-directed teams that are engaged in highly precise and exact work where errors can result in great health, financial, or welfare risk. For example, in a medical laboratory, the quality control that was maintained by the first-line supervisor in a hierarchical organization is now maintained by the team itself in a matrix organization of self-directed teams. The result is that all team members must be highly trained, or a team member must take on the role of a quality control expert. If the latter is done, this must be communicated to all team members, and that person must have authority to insure quality control of all critical processes carried out by the team.

Many environmental and social factors have pushed the evolution of organizational structures. Three main principles impinge on

organizations: 1) technology, 2) growth of knowledge, and 3) globalization.<sup>3</sup> First, the increased technology available allows a company's internal and external barriers to be broken down. Computers and computer-based technology have changed the flow of information. Likewise, technology has allowed many laboratory tests to be automated. Second, this increase in information or knowledge, which often has been the source of power in organizations, now is at a worker's disposal. The third key to changing the organization is the globalization of business. Companies now must compete globally for customers. Using improved technology allows companies to operate at a frenzied pace. The benefits of teams can be summarized as follows: (1) For the organization, teams provide more productivity, lower personnel costs, and allow more responsive actions to be taken to meet customer needs. For the individual, teams provide for integrating skills, tapping all staff resources, more stimulation, energy and emotional support for staff members, more sustained effort at meeting team goals, and greater satisfaction with work.

### **Steps in Setting-up Work Teams.**

Research shows that the following steps should be taken to effectively introduce and establish work teams in an organization: (1) Secure top management support; (2) Assess the climate of the organization to determine if it is ready for teams; (3) Set up a planning committee to investigate the team approach, to visit sites where teams are working, and to study the organization and its needs; (4) Set up the organizational structure for teams; the individual teams, team leaders, and coaches; (5) Train staff to work in teams; and (6) Continuously evaluate the program to maximize opportunities for making

improvements.

Two key positions affect how teams operate: the team leader and the coach. The team leader calls meetings of the work group, keeps records of progress, coordinates training, and does other leader roles with the group. Usually when teams are introduced to an organization, the leader is appointed by management. After the team is functioning for some time (1½ to 2 years), the team itself picks its leaders or the leadership role is rotated among the members. The coach is usually a manager in the organization who is responsible for insuring that the team is staying on track. He/she usually directs several teams. The coach, however, can be the team leader. The members of the team enjoy the privileges of empowerment as well as challenges of continuous improvement. Quality can be assured by continuous feedback or the use of a team member as a quality control expert.

By definition, a work team is a cohesive unit of highly motivated, highly skilled and highly trained workers who supervise themselves with the encouragement and direction of a coach. Although there are several types of teams, two that we are most familiar with are: (1) Parallel teams which exist in parallel to or in addition to the established organizational structure; and (2) Project teams which are temporary, special-project groups of people who are brought together to complete a project. The work teams we are discussing here, however, are permanent structures that function as integral parts of an organizational structure to accomplish the work.

In establishing teams, several questions must be kept in mind: What will the organization look like one or two years from now? How can we meet competition and lead and manage our business as we continue

to push for higher quality and productivity? In what ways will we need to reengineer<sup>4,5</sup> and change our current processes, jobs and culture to support the future business of the laboratory? How can we meet the legal requirements for a clinical laboratory when we are using teams of people from different disciplines?

The management literature points out that for teams to succeed, the following must be true. First, trust between management and staff is an absolute requirement for successful teams. Actions of management and employees must reflect the belief that (1) people can be trusted to make important decisions about work activities and (2) that people can acquire the knowledge to make important decisions about managing of their work activities.

You can assess your readiness for moving to teams. You can develop your own survey, use those reported in management books on teams, or hire a consultant to do this assessment. The Environmental Protection Agency uses an effective survey for this purpose.<sup>6,7</sup> Also, the Organizational Assessment Survey (OAS) of the U.S. Office of Personnel Management is available for use.<sup>8</sup> It is recommended that the use of materials like the OAS should be done by trained organizational specialists. The survey can identify where the organization is not working well and identify the areas that need to be examined more carefully. This survey is in the public domain; comparison data are available from the U.S. Office of Personnel Management (OPM) for sharing, provided the survey users share their data with OPM.

### **Staff Performance Appraisals.**

An important issue is how to conduct performance appraisals on team members.

Since the team itself is more important than the individual workers, employees can be evaluated on the overall success of the team. Particularly outstanding contributions can be recognized by a plaque or monetary reward. Most research studies of teams suggest that individual awards be kept to a minimum and that team awards should be frequent and varied. Many think that the traditional performance appraisal should not be used for individuals in teams. The reason for this is that no one person is familiar with all of the activities of an individual employee who may be on two or more teams. One alternative method is to use what is called the 360° rating.<sup>9,10</sup> Usually this type of rating takes input from many sources, peers, subordinates, superiors, customers, etc. Although it is usually limited to identifying training and development needs, it can be used for performance appraisal. This rating is based on self, peer, and management input on the level of competency and task expertise the person shows and the need for training and development to improve this competency and task performance.

### **Program Evaluation**

It is important to evaluate the progress of an organization when it moves to teams. Because of the critical nature of clinical laboratories, a quality control and program evaluation effort is important. For this program, continuous and follow-up evaluations should be made. These should include error rates, costs, other outcomes, and training and development needs assessment. Several forms of evaluation can be used; for example, anonymous surveys of employees and management can be made. Likewise, surveys of customers should be conducted. A complaint or suggestion box and perhaps a telephone hot-line should be

established.

Because technology has increased the available information and allowed for easier, more rapid communication, an organization must structure itself in a manner that facilitates and utilizes its resources. The new organization has few upper management positions. The workforce is usually divided into teams; moreover, the members of teams usually work on more than one team. Information disseminates via the teams, computers, and telephones/facsimiles. No formalized chain of command or channels of communication may exist. Everything flows throughout the organization unimpeded; thus, the boundaries of old hierarchial organizations are broken down and flattened. Technology, growth of information, and globalization define the new organizations. Speed and efficiency are increased and service quality is enhanced.

Organizations will continue to flatten as companies strive to cut costs without sacrificing speed, efficiency, and, most importantly, product quality. Usually, teams go through developmental stages; it often takes 2 to 3 years for a team to mature so that it is functioning at its maximum efficiency. Each team member may be an expert in a different aspect of a process. A team, however, is usually established to carry out one or a few entire processes for a customer.

As a final note, if you are considering moving to a team approach in your laboratory, you should remember 4 things:(1) Teams are not a panacea for all problems. A traditional, hierarchial organization can and will run very effectively for most laboratories. (2) Your organization should not jump in and set up teams without careful planning. You should establish a planning committee. This committee should

have representatives from all of the disciplines in your laboratory and from management and staff, as well as union representatives, if you have a union. The team should make site visits to organizations where teams are functioning well. You should plan to have this committee work for a minimum of six months in planning. (3) You do not need to change to teams for all organizations within your laboratory. Some may not be ready to go to teams. This is OK. However, you must have top management support for teams or they will not work. (4) You must be willing to spend more time and money on training. To be maximally effective, team members must be well trained. Team leaders may need additional training.

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## Future Needs For A Clinical Laboratory Workforce

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**Abstract:** Market forces are radically altering the U.S. health care system. The changes we see today and those that we can reasonably predict for the future will undoubtedly alter practice patterns. The number and types of personnel, the skills they will require, the systems within which they will practice and their relationships with other providers are all critical factors in assessing of practitioners for the future.

The ongoing pressure from the purchasers of health services and the public's demand for the highest quality of care have increased competition in the system. Managed care organizations are ever turning their attention toward primary care with a heavy emphasis on health promotion and disease prevention. Hospitals and other care environments are seeking the greatest possible flexibility in their options for personnel utilization, and they are developing less hierarchical management structures. Interdisciplinary, self-directed work teams are entering the marketplace, with less reliance on traditional personnel.

With advances in technology and more sophisticated information systems, the question must be raised about whether the skills of today are adequate for practitioners of the future; in addition, will be the appropriate roles of health care providers with specialization in laboratory services?

Given all that we know and have heard about the nature of health care delivery in 1995, I believe that a few predictions about the future are easily conceived. As we look to the turn of the century we see:

- more decentralized care - fewer hospitals with care provided at a variety of different types of facilities;
- less distinct boundaries between the disciplines - credentials will be broadened and the number of multi-skilled providers will increase;
- greater emphasis on self-care and self-determination of care. Increased use of home test kits and health promotion disease prevention strategies;
- increased use of technology. Home computers linked to large data bases for self-diagnosis, a biochemical diagnosis of cancer and body monitors for ongoing physiologic assessments are all feasible technological advances;
- that information and its use becomes a more important issue for professional laboratory personnel than performing the tests;
- a more rational health care system with greater integration of its components.

In this time of rapid change in the health care delivery system, there has been a great deal of focus on increasing access, reducing costs and maintaining quality. As the pace of change accelerates, it becomes increasingly clear that the health care workforce has not been the driving force for this change. Personnel shifts have been resisted by the professionals, with payers determining the shape of the workforce. Many people believe that we simply do not have the right type of providers, in the right numbers, in the right places, doing the right things. Thus, to ensure accessible health services at a cost-effective level, we must educate laboratory practitioners to their role in managing the change occurring throughout the health care system.

The Center for the Health Professions at the University of San Francisco has studied the current status of the health care system and identified the following tensions that are shaping the system:

Specialized Care	↔	Primary Care
Technological	↔	Humanistic
Cost Unaware	↔	Cost Aware
Institution Focused	↔	Ambulatory/ Community Focused
Professionally Governed	↔	Managerially Governed
Acute Care	↔	Chronic Care
Individual Patient Population Perspective	↔	
Curative Care	↔	Preventive Orientation
Content Mastery	↔	Process Mastery
Individual Provider	↔	Team Provider
Competition	↔	Cooperation
Current	↔	Re-regulation

These tensions have emerged in great measure because of our strong focus on practitioner competence within each discipline. Discipline competence, however,

is only one type of competence with which we must be concerned; today's practitioner must also possess social and cultural competence.

**TABLE I**

**DISCIPLINE COMPETENCE**

- Skill with the performance of discipline-related tasks
- Knowledge of theory within the field
- Critical thinking and decision-making related to a particular role

**SOCIAL COMPETENCE**

- Ability to communicate within and outside field
- Knowledge and understanding of roles of others
- Ability to work in teams

**CULTURAL COMPETENCE**

- Recognition of the cultural determinants of the agency, institution or system
- Acquiring the cultural characteristics of the discipline and the larger environment
- Respecting and sharing perspectives of others

In 1994, the Pew Health Professions Commission delineated 17 competencies which all health care providers must be able to demonstrate in the year 2005. These competencies are multi-faceted and encompass the range of social and cultural abilities needed in health care as well as the discipline, specific knowledge and skill appropriate to practice. They require flexibility, multiple skills, interdisciplinary team-directed practice and collaboration

across levels of providers.

**TABLE II**  
**COMPETENCIES FOR 2005**  
**PEW HEALTH PROFESSIONS**  
**COMMISSION**

- Care for the Communities' Health
- Expand Access to Effective Care
- Provide Clinically Competent Care
- Emphasize Primary Care
- Participate in Coordinate Care
- Ensure Cost Effective and Appropriate Care
- Practice Prevention
- Involve Patients and Families in the Decision Making Process
- Promote Healthy Life Styles
- Assess and Use technology Appropriately
- Improve the Health Care System
- Manage Information
- Understand the Role of the Physical Environment
- Provide Counseling of Ethical Issues
- Accommodate Expanded Accountability
- Participate in a Racially and Culturally Diverse Society
- Continue to Learn

In today's laboratory practice environment we continue to focus most of our attention on the skills associated with the

performance of tests and the knowledge related to those techniques. Conversations about personnel standards place a higher priority on the ability to detect performance error rather than the other abilities inherent in the Pew competencies. The delayering of the workforce with the elimination of many mid-level positions raises concern for the amount of supervision that is feasible in the laboratory. The cross training of boundaryless teams to create "affinity clusters" of multi-skilled practitioners is a trend that is being debated.

Each of these issues is complex. We have no standards for continued competence beyond the entry level. The demands of different workplaces demand different personnel. Is testing truly site neutral?

Questions for research which evolve from these issues include:

1. What number and types of laboratory personnel will be needed in the 21st century?
2. Are there meaningful outcome differences in professional competence among the various educational levels of practitioner?
3. What types of personnel credentials are most effective in demonstrating competence?

## **Summary of Workshop #2: Personnel**

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**CDC Liaison: John Ridderhof, Dr.P.H.**

### **Key Questions:**

- 1) Are the knowledge and skill requirements for personnel currently used by the laboratory community adequate to ensure personnel competency?
- 2) How can knowledge and skill requirements and personnel competencies be better assessed in the future?

Personnel issues, particularly personnel standards and competencies, have been one of the central issues in assuring the quality of laboratory practices. Personnel standards combined with regulations for quality control and proficiency testing are the backbone of the Clinical Laboratory Improvement Act (CLIA) of 1967 and the 1988 CLIA Amendments.

Examining the connection, however, between personnel standards and the quality of laboratory testing is a difficult exercise. Numerous confounders and interactions exist. Personnel competencies can be potentiated or negated by the quality of the administrative structure, technologic sophistication of the instrumentation, rigor of the quality assurance program, and ability of the system to optimally use and benefit from quality laboratory testing. Research examining the relationship between personnel qualifications and laboratory outcome does not control for these factors, nor conduct prospective studies, and nor incorporate clinically appropriate outcome measures.

This leaves the question of the connection

between personnel standards and quality laboratory testing unanswered and subject to political processes. Some argue that personnel standards must be eliminated because no well-designed study documents that they make a difference. Others argue the reverse: personnel standards must be retained because no study demonstrates that relaxing the standards would not harm patients. Therefore, until well-designed and controlled prospective studies are completed, the future is more likely to be guided by political power rather than scientific evidence.

Five panel members provided guidance on these issues. Dr. Karen Karni, University of Minnesota, presented two studies: 1) laboratory staffing patterns in Minneapolis-St. Paul area hospital and HMO laboratories and 2) the error rates in 19 satellite HMO laboratories and their distribution between AS- and BS-prepared laboratorians. Dr. Barbara Castleberry, American Society of Clinical Pathologists Board of Registry, discussed a 10-year longitudinal project being undertaken by this board. The project will yearly survey a cohort of individuals



who took the 1993 examination to determine their job characteristics, satisfaction, career advancement, and other issues. Dr. Michael Peddecord, San Diego State University, described a task analysis project and the input that was received from a focus group of supervisors queried about personnel characteristics which should produce superior performance in the laboratory. The fourth panelist, Mr. John Kraft from the U.S. Office of Personnel Management, discussed the need for teams, team cooperation, and team-building skills for the rapidly changing environment. Dr. Glenda Price, Spelman College, concluded the panel with a summary of the core, cross-disciplinary competencies recommended by the Pew Commission for the Health Professions for all health professions; she then discussed the implications of these recommendations to the educational preparation of future laboratorians.

Among the topics raised in the discussion following the panelists' presentations, workshop participants questioned the validity of research studies which make associations between personnel standards and performance in laboratory proficiency testing programs. They concurred that proficiency testing is a flawed proxy for directly measuring the quality of daily laboratory testing within the context of the total testing process. To judge the appropriateness of personnel standards by outcomes achieved on proficiency testing samples is an incomplete assessment in that it evaluates only the analytical component. Even if proficiency testing samples are truly processed as routine specimens rather than marked for special treatment, proficiency testing still fails to capture the expertise needed in the pre-analytical and post-analytic portions of the total testing process. The

participants agreed that pre- and post-analytical factors must be included in the assessment of competencies.

With this in mind, the workshop participants examined the key questions. Discussions led to agreement that these questions needed to be broadened to include the total testing process as well as economic and social factors that influence the current changes within the American health care delivery system. The 22-member workgroup divided into four subgroups to further refine the question, and then convened as a committee-of-the-whole to develop a composite question.

The revised and consolidated question addressed by the workgroup is:

*Recognizing customer needs, dynamic health care environment, and various practice settings, what are the required knowledge, skills, abilities/values, and other characteristics (KSAOs) to ensure effective, efficient, value-added performance of all laboratory processes (total testing process) impacting the quality and cost of patient care?*

We reconvened in our four subgroups to determine what research agenda was necessary to answer our revised question. Each subgroup developed its own agenda which was shared with the committee-of-the-whole. Group consensus was then reached on the highest priority topics. A 2-part agenda resulted: total testing performance, and management/supervision.

### **Research agenda to ensure competency throughout the performance of the total testing process**

1. What personnel characteristics and behaviors contribute to an effective outcome (value-added patient care)? Based on early qualitative research concerning the

characteristics of superior laboratory staff, personnel characteristics, behaviors, and values appear to make a difference. However, what are these characteristics, are they teachable, and do they make a difference in achieving an effective outcome for the patient? Do they improve the analytic result, but more importantly, do they add value to the total testing process and improve patient outcome?

And what is that extra value? How would patients' outcomes differ with and without quality laboratory performance? How can we identify that extra value and maximize the incremental contribution?

2. For each phase of testing, what are the measures of quality performance? We had quantitative measures to evaluate the analytic component of laboratory testing, but what are the clinically relevant measures for the pre- and post-analytical components?

3. What is the role of laboratory personnel in improving laboratory utilization and the interpretation of test results? If we can identify measures of quality performance, what is the role of laboratorians and what is the role of clinicians, nurses, computers, and administrators in improving the total system of laboratory testing? When the role of the laboratory is defined, how can measuring these factors be incorporated into our total quality assurance system?

4. What are the KSAOs needed to improve interventions in pre- and post-analytic phases?

- What basic and applied medical science knowledge/skills will be needed?
- What communication skills will be needed?
- What "people-skills" will be needed

to interact with the health care team?

Once we identify our roles, what are the KSAOs needed to ensure we perform these roles well? Participants agreed that these roles will extend beyond our scientific knowledge and must include communication skills both to transmit laboratory information as well as to be effective members of teams within the laboratory as well as effective members of the more comprehensive health care team. We must communicate better to improve laboratory utilization and test interpretation.

5. Are the current KSAOs appropriate to develop and implement actions to improve test utilization and interpretation? Once we identify what is needed, next we must determine if the present KSAOs are appropriate. Should new educational modules or continuing education programs be developed to achieve the identified KSAOs?

6. Is there variation in performance/quality among practice sites? How will we measure that variation? What other methods exist or must be developed that extend beyond proficiency testing? Are different levels of performance acceptable in different sites? What is the incremental gain of increasing laboratory quality across sites?

7. What systems knowledge is needed to manage the testing process to improve:

- overall system performance?
- the analytical outcome?

8. Does the level of training lead to the reduction of errors in all phases of testing? This is the final summative question. If we identify how laboratorians can make a

difference in improving all phases of the total testing process, if that the improvement does lead to better patient outcomes, if the KSAOs needed to achieve that improvement can be identified and taught, does the inclusion of this material and the level at which it is taught result in a reduction of errors? And does a reduction of errors lead to an improved patient outcome?

### **Research agenda for management/supervision competency**

9. What skills/knowledge are needed to plan, organize, direct, and control outcomes-based processes? Supervisors and other management personnel also will need to examine the KSAOs needed in an outcomes-based laboratory effort. These extend beyond the technical expertise and may include interpersonal skills and administrative abilities to plan, organize, direct and then control laboratory processes which have their focus of improved patient outcomes, rather than an analytically precise and accurate laboratory result.

10. How do we assess the KSAOs of personnel supervising off-site testing? Much laboratory testing will be performed off-site without direct supervision. This could include bedside testing as well as testing in the home, physician office laboratories, ambulatory clinics, and wellness fairs. What supervisory skills are needed for these environments, how do we assess these skills, and how do we assess the KSAOs of the individuals performing in these off-site testing locations?

11. Who evaluates whom in a team structure? By its very nature, a team consists of a group of individuals. If the team is evaluated, do its members need to be individually evaluated also? Within a team, who evaluates whom?

### **Research agenda for evaluation of competency**

12. What competency assessment tools are most effective/accurate in measuring laboratory scientists' ability to add value to a positive patient outcome? We have a measurement problem. Central to many of our previous research questions is a need to develop accurate and effective competency assessment measures. How can we determine if laboratorians add value to a patient outcome if we only have certification examinations and proficiency testing results as competency measures?

These 12 questions map a comprehensive research agenda which will require qualitative descriptive studies as well as prospective controlled trials. Much preliminary work must be performed if we are to operationalize the concept of the total testing process and build the identified competencies into the preparation of present and future laboratorians. In an environment of constrained health care dollars, we must demonstrate that these revisions in the nature by which we do our business make a contribution to a more efficient and effective health care delivery system. Only then can we link identified and necessary personnel competencies to a value-added contribution by the laboratory community to improved patient care.