USE AND PERCEIVED VALUE OF PROFICIENCY TESTING IN THE CLINICAL LABORATORY

APHL Report

JANUARY 2012

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

The Association of Public Health Laboratories (APHL) is a national non-profit organization dedicated to working with members to strengthen governmental laboratories that perform testing of public health significance. By promoting effective programs and public policy, APHL strives to provide member laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

Prepared by Willis Consultants, L.L.C. for the Association of Public Health Laboratories (APHL).

This report was supported 100% by Cooperative Agreement Number #1U60HM000803 from CDC.

Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Proficiency testing (PT) provides reassurance for the clinical laboratory that its results are accurate and offers objective evidence of laboratory competence. This study explores how clinical laboratorians use and perceive the value of PT beyond meeting the regulatory requirements and describes categorical observations and experiences related to the use and value of PT in the laboratory.

In this study, funded by the Centers for Disease Control and Prevention (CDC) through a cooperative agreement with the Association of Public Health Laboratories (APHL), focus groups were conducted to obtain information from laboratorians responsible for PT in their respective facilities. Topics were agreed upon by a team of subject matter experts from CDC and APHL and key questions with probes were developed based on the topics. Focus group responses to the key questions and probes regarding the use and value of PT and satisfaction levels with PT provider services were analyzed using an "immersion-crystallization" framework[1,2] involving successive cycles of textual data review. Insights from this process were further used to develop categorical summaries to provide clarity regarding participating laboratorians' perceptions of PT.

The focus groups were comprised of 60 laboratorians with supervisory responsibilities for PT from large and small laboratory testing facilities, microbiology (micro) departments and public health laboratories (PHLs). Seven focus groups were conducted in four locations in the United States. (See Table 1 in the Methodology section for the breakdown of participants by group location and facility category.)

These focus groups revealed that while laboratorians acknowledge the regulatory benefit of PT, they also view PT as an opportunity to demonstrate and measure ongoing competency, to provide education and training to testing personnel, to evaluate their analytical processes, to evaluate new methods or technologies, and to enhance their quality improvement activities.

Regardless of type or size of facility, participants repeatedly stated that the most important benefit of PT was its ability to increase confidence in the quality of a laboratory's performance

and its use as a quality indicator for stakeholders at various levels. The value of PT for staff competencies, peer group comparisons and educational opportunities followed close behind in importance. Many laboratories extend the value of PT over time by using materials such as PT slides and photomicrographs as ongoing training resources. PT sample materials remaining after results submission to PT programs are used for verification of results and to maintain stock cultures of organisms.

While there were many instances in which the perception and the use of PT were similar for all groups, large laboratories, microbiology departments and PHLs tended to approach PT testing from a system-wide perspective. Their issues with PT mainly focused on overall PT program requirements and services. Smaller facilities tended to focus more on the daily pressures of inadequate staff numbers and administrative responsibilities in addition to laboratory management and testing. Unlike their counterparts in larger facilities, meeting the requirements for PT testing was sometimes seen as onerous for smaller laboratories to balance with their other daily responsibilities.

Based on the findings of these focus groups, potential future training activities could include: exploring specific educational needs for new laboratorians and health professionals with little laboratory background on the value and uses of PT; developing a training session to enhance physician office laboratory (POL) awareness and address the differences between PT and quality assurance (QA); and creating training to assist supervisory staff in effectively using PT to assure regulatory compliance and as a quality improvement tool.

A review of the responses of these seven groups also suggests that developing, distributing and analyzing a larger nationwide survey based on the key themes and topics represented in these focus group responses could be useful in broadening the findings of this study.

Laboratorians participating in these focus groups were extremely professional in their responses. They were all committed to the highest quality of laboratory work and appropriately concerned about issues that they believe could prevent them from contributing to optimal performance and continuous improvement in their laboratories.

I. INTRODUCTION

The public's health depends on the provision of high quality clinical laboratory testing services which are critical for diagnosis and treatment of patients, for epidemiologic surveillance of disease outbreaks, for assessment of the status of the public's health, and for identification of sentinel cases of environmental contamination.

Proficiency testing (PT) provides reassurance for the laboratory that its results accurately represent true patient values and offer objective evidence of laboratory competence for regulatory agencies and accrediting organizations. Participation in a PT program approved by the Centers for Medicare & Medicaid Services (CMS) is an integral part of a laboratory's quality management program and is required under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

While there are studies that indicate the value of a PT program in maintaining and improving the quality of laboratory results[3,4,5,6] there is limited information on the value of PT from the perspectives of the laboratorians who perform the PT. As a first step to obtain information from the laboratorians' point of view, APHL conducted an informal survey (Appendix A) of approximately 30 laboratorians and laboratory managers at the Clinical Laboratory Management Association (CLMA) May 2010 ThinkLab meeting. They were asked about their use of PT for reasons beyond meeting regulatory requirements, how the results are used to improve the quality of testing in their laboratories, their observations on the benefits and challenges of PT and their satisfaction with the services of the PT programs in which they are currently enrolled. Results from this survey were used to build the focus group questions and probes.

This data summary report offers detailed analysis of the data collected in 2010 and makes comparisons to the 2007 data where available.

II. METHODS

A. Participant Selection and Recruitment

Laboratorians with supervisory or managerial status and decision-making responsibilities related to PT were recruited from hospitals, independent, public health laboratories, and POLs located in geographic zip codes and telephone area codes that were within an approximate 50-mile radius, or less than one driving hour, of the focus group site selected for that session.

Four facility categories were defined for inclusion in the focus group sessions: large multispecialty laboratories, small multispecialty laboratories (including POLs), public health laboratories (PHLs) and microbiology departments from a variety of laboratory sizes (Micro). Using the CMS Online Survey Certification and Reporting (OSCAR) database, facilities qualifying as large laboratories, regardless of specialty, were identified as those with a yearly test volume greater than the median OSCAR database volume of 300,000 tests. Small multispecialty laboratories were identified as those with a yearly test volume less than that 300,000. Microbiology laboratories or departments were identified as those laboratories listed in the OSCAR database as conducting microbiology testing. Public health laboratories were identified through the APHL database.

One microbiology focus group was scheduled to coincide with the American Society for Microbiology (ASM) 111th General Meeting taking place in New Orleans, May 21-24, 2011. Qualified participants were identified from the OSCAR database (in an effort to include some facilities in the local greater New Orleans area) and 590 microbiologists who had previously participated in APHL trainings who might be attending the ASM meeting were invited to complete an online application containing the same questions that were used in the telephone recruitment tool. An attempt was made to balance geographic location and laboratory size in selecting focus group participants from those who completed the online application.

Participants in the fourth group, public health laboratories, were identified by APHL. Both local and state public health laboratories were recruited from the Northeast region, and one Food /Agriculture laboratory in Florida was recruited. An effort was made to recruit a geographically diverse cross section of primarily “true, stand-alone” PHLs, defined as those not functioning as part of a university hospital system. Due to limitations of cost and feasibility of cross-country travel for a single 2-hour meeting, invited PHLs west of North Dakota were unable to attend and are not represented in the study findings.

Attempts were made when recruiting both large and small laboratories to balance the distribution of recruited facilities to include both Certificate of Compliance (CoC) laboratories inspected by CMS only, and Certificate of Accreditation (CoA) laboratories, which are inspected by a CMS-approved accrediting organization for CLIA purposes. All laboratories must meet the minimal CLIA requirements for PT participation while accredited laboratories may also be required to meet requirements that exceed those specified by CLIA.

Participants from smaller laboratories were more difficult to recruit. An observation from the APHL staff who conducted the phone recruitment was that often non-laboratory or administrative personnel screened calls and acted as gatekeepers, preventing telephone recruiters from actually accessing the person performing the laboratory testing to offer the opportunity to participate. In addition, it was noted that positive response was lower when the person responsible for the testing was not a laboratorian. Due to the poor response from this group, it was not possible to get equal numbers of participants from CoC and CoA facilities as initially planned.

B. Participant Demographics

A total of 60 laboratorians participated in the seven focus groups in four locations (Atlanta, GA, Houston, TX, Boston, MA and New Orleans, LA) January through May, 2011. With the exception of several participants in the New Orleans microbiology session, which recruited participants nationwide, two sessions each were conducted with laboratorians from large facilities (>300,000 tests annually), small facilities (<300,000 tests annually), and microbiology departments, while one session was conducted with laboratorians from PHLs.

Table 1: Breakdown of Participants

Locations	Large Laboratories	Small Laboratories	Microbiology Laboratories	Public Health Laboratories
Atlanta	7	5		
Houston		8	6	
Boston	11			11
New Orleans			12	
Totals	18	13	18	11

There were 13 participants representing small facilities, 18 participants representing large facilities, 18 participants representing microbiology laboratories and 11 participants representing public health laboratories. Of the 60 facilities represented, nine (15%) self-identified as CMS/CoC laboratories; the remaining 51 (85%) reported being accredited by CMS-approved organizations. Of the PHLs, five (46%) of the 11 facilities represented identified themselves as CoC laboratories. Of the 13 small facilities represented, five (39%) were classified as POLs; of those five POLs, four self-identified as CoC laboratories.

Of the 18 large laboratories represented, 13 considered themselves part of a centralized laboratory network for a hospital or clinic, one represented a university/medical school teaching hospital, two were from POLs and of the remaining two, one participant represented an independent laboratory and one represented the laboratory manufacturing industry (in which the other participants are its potential customers). All 18 facilities employed mainly

clinical laboratory scientists (CLS)/medical technologists (MTs) with baccalaureate degrees (BS) or clinical laboratory technicians (CLT)/medical laboratory technicians (MLTs) with 2-year associate degrees (AA); several large laboratories, including the two larger POLs and the industry manufacturer, also reported testing personnel at Master of Science (MS), Doctor of Philosophy (PhD) or Doctor of Medicine (MD) educational levels. All of these facilities were enrolled in accreditation programs, many maintaining multiple certifications (such as toxicology or forensic certifications) in addition to their CLIA certifications.

Of the 13 small laboratories and POLs represented, six self-identified as hospital laboratories, five were POLs and two were commercial laboratories. Almost all facilities employed CLS/MTs at the BS level and/or CLT/MLTs with 2-year associate degrees, although one commercial laboratory included PhD or MD education in its staff background and one hospital clinic laboratory employed nursing staff at the Baccalaureate in Nursing (BSN) level to perform laboratory testing. Testing personnel at the MS level were included only at the 2 commercial facilities. Of the 13 small laboratories, four were CoC laboratories and the remaining nine were enrolled in at least one accreditation program, a few with more than one additional non-CLIA certification. Of the five POLs represented in this group, four were CoC laboratories while the fifth POL was accredited by COLA.

Of the 11 public health laboratories represented, one was a state agricultural laboratory, two were local public health laboratories, and the remaining eight were state public health laboratories. Testing personnel in all 11 facilities had received laboratory training, education and certification at the baccalaureate and associate degree levels, while just more than half of the laboratories also included testing personnel at the MS level and one third of the laboratories also had testing personnel at the PhD or MD level. Of the 11 facilities, five were CoC laboratories and six held certificates of accreditation plus other non-CLIA certifications.

The 18 participants from microbiology specialty laboratories represented 13 large hospitals and four university/medical school teaching hospitals, with one local public health department also participating. Almost all laboratory testing personnel (17/18) in these facilities were CLS/MTs at the BS level and half of all laboratories also had CLT/MLTs with 2-year associate degrees; just over 27% (5/18) also included graduate level (MS, PhD, MD) personnel. With the exception of the local public health department, which is a CoC laboratory, all microbiology laboratory participants represented accredited laboratories.

C. Data Collection

Data collection was conducted through a series of semi-structured focus groups in which primarily supervisory/management level clinical laboratorians with PT responsibilities discussed experiences with PT in their facilities. The same focus group moderator was responsible for conducting all seven focus groups, and the same note taker was used for all seven focus groups. The note taker compiled real-time notes of individual statements, observations, opinions and concerns as well as summary notes from the recorded sessions. Participants were made aware that investigators from APHL and CDC were observing behind one-way glass to view the group process and to provide additional questions to the focus group moderator if needed for clarification.

Topics for the moderator's guide (Appendix B), consisting of three major questions supplemented by probes, were structured based on the answers to the CLMA ThinkLab '10 meeting questionnaire with input and guidance from the subject matter experts at CDC and APHL. Probes for each question were further clarified based on the responses of the first focus group. The same questions were asked at each focus group, with the various probes used to expand the questions if needed and to obtain additional depth if participants did not offer enough detail in their answers.

Informed consent for participation (Appendix C), audio-recording and site observation was obtained from all participants at the beginning of each focus group. Information on each participant was collected from the recruitment tool (Appendix D), which was a survey to determine the eligibility of participants; an on-site, number-coded questionnaire (Appendix E); and by verbal input using first name only at the focus group meeting.

D. Data Analysis

The moderator's process observations, the note taker's notes and the audio-recordings of each session established the content basis for analysis, generated initial categories and influenced minor formative edits of the moderator guide and probes for the group sessions that followed.

Key repeating words, terms and phrases from the transcripts and recordings of all sessions were manually identified and recorded by category, set into a structural outline and were used as headings in the final report. Emerging common themes were analyzed using immersion-crystallization, a 'qualitative analytic style in which concentrated contextual review of data is combined with reflection and intuitive insights until reportable interpretation becomes apparent.[1,2]

III. RESULTS/MAJOR FINDINGS

Regardless of facility size, participants repeatedly stated that the most important benefit of PT reported by these laboratorians was increased confidence in the quality of a laboratory's performance along with its value as a quality indicator for stakeholders at various levels, with staff competencies, peer group comparisons and educational opportunities close behind in importance. Many laboratories use PT materials such as slides and photomicrographs as ongoing training resources, and leftover PT materials are used for rechecking results, conducting competency evaluation of staff and maintaining stock cultures of organisms.

While the majority of participants were laboratorians with responsibilities for PT in their facilities, there were two respondents who shared alternate perspectives. One recently-graduated, newly-employed laboratorian from a small facility considered the focus group discussion an "eye-opener" and an educational experience. He interacted with the other participants in getting advice for his own facility and requested information on contacting the appropriate PT experts for consultation before the next PT survey arrived in his laboratory. He left the meeting enthusiastically determined to use PT in some of the ways he had heard discussed.

Another alternate perspective came from a participant who was from industry representing an instrument manufacturer, and the question of the value of PT in his organization was briefly explored. His observation was that PT is a way to understand what is happening in customers' laboratories and to inform management about the performance of new instruments and analyzers that his company develops. His opinion was that PT serves as a great evaluative standard and that his company uses PT to experience what their customers might be experiencing and to compare and test materials that may be problematic for customers. From his perspective, PT supports good public relations and allows his company to provide effective support for their instruments by being more aware of potential problems and minor issues before they cause serious issues.

Information was shared by all participants during the group discussions on the relationship of PT to overall quality assurance including: the analytical process, personnel competency, benefits and challenges of PT in large, small, microbiology and PHL laboratories and confidence in laboratory results. Further discussion addressed satisfaction with provider services, which encompassed samples, methodology, timetables, ungraded challenges and provider information. Four consistent topics emerged and are further discussed in the next paragraphs. In addition, findings from microbiology specific discussions are also included in this section.

A. PT Sample Identification/Handling
B. PT Use in Quality Management
C. PT Benefits and Challenges
D. PT Program Services Satisfaction
E. Microbiology Specific Topics

A. PT Sample Identification/Handling

One of the most commonly shared frustrations in all groups was the CLIA requirement to treat PT samples the same as patient specimens. Concealing the identity of these samples as PT materials is difficult or impossible since the samples themselves often do not appear the same as patient specimens, and PT guidelines sometimes require additional instruction on handling and testing the sample and reporting results. It is often analytically and administratively impractical to treat PT samples as patient samples, and it frequently requires additional work than would be required of a patient sample. Additional documentation required of PT samples and results also raises the potential for transcription error, as this documentation is not necessarily part of testing patient samples.

Most participants distinguish PT samples as non-patient samples in some way, although it is difficult to keep the identity of the sample confidential when the sample matrix or sample results are not similar to those that could be reasonably expected from patient specimens. When they must be reconstituted or otherwise treated differently, PT samples must be identified as such and so cannot be treated as patient specimens even as a good faith attempt is made to follow the same protocols as in patient testing.

According to several participants, only in forensics laboratories where all specimens are blinded per strict laboratory protocol could a specimen be easily blinded. “In the rest of the laboratory world, it is difficult if not impossible to blind a PT specimen. In the clinical setting, everybody knows!” From a personnel perspective, most laboratory testing personnel are aware of the PT sample as such. They may give more or different attention to handling and result reporting to the PT sample than is given to the routine patient specimen, knowing that the laboratory’s accreditation status could be affected by their PT results.

From an administrative perspective, blinding PT samples is usually not an option although a few facilities are able to enter some PT samples as patient specimens. Some facilities blind their PT samples by having their Information Technology (IT) department assign PT samples identifiable codes that can later be used by IT technicians to pull those sample results from the testing runs. Many reported that they “order the sample as a patient but do not result the sample as a patient.” For many, there is a practical need to be able to identify PT samples so that PT results can be pulled from electronic laboratory systems before those entries introduce errors by skewing the data that will be collected for trending, billing systems, data collection records, workload units and epidemiology. PT entries can introduce errors in computation and conclusions for non-analytical purposes.

B. PT Use in Quality Management

All participants acknowledged that enrollment and successful participation in a CMS-approved PT program was necessary to maintain the required CLIA certification/accreditation for performing laboratory testing. Although the initial response of most of the small facilities and POL participants was that they “did PT because they had to do it” to maintain certification/accreditation, additional probing questions indicated that their overall uses were remarkably similar to larger laboratories. Only one small laboratory, which functioned within an emergency room setting, reported using PT for regulatory purposes only.

Practical uses of PT in overall quality management were remarkably similar in all groups. Most see PT as valuable in testing the accuracy of their systems, validating new instrumentation, verifying accuracy in user-developed analyses and troubleshooting analyzers. They also use the information in PT summary reports to support recommendations in methodology or instrument changes to upper management, often choosing vendors based on the PT performance of their products. They review the peer information provided by their PT program to confirm that the number of laboratories using a new instrument or methodology is sufficient to allow that PT program to provide a grade and offer peer comparisons before they change methodologies or instruments. All groups value PT for personnel competency assessment, educational opportunities and improvement of the testing process, although the smaller laboratories that were short-staffed were often not able to maximize the potential for using PT in training exercises.

In addition to the analytical, competency and educational applications of PT, several noted that PT scores can be used in defense of quality of testing and results with upper management and are occasionally successfully used to defend laboratory results when challenged by a clinician.

1. Competency/Education & Training

Aside from meeting regulatory requirements, most participants reported that the two most commonly cited uses of PT testing in quality management programs were for demonstrating employee competency and staff education/student training, both of which they viewed as integrated activities that coordinate improvement of staff skills. Many felt that PT could be used to identify which staff may require more training in a particular area. Some reported that they used the samples as unknowns for assessing new-hire competencies. Some viewed PT challenges as “a chance to stop and refresh your knowledge.”

Participants from most of the smaller laboratories stated that they used left-over samples for staff education or retraining. Most participants from the larger laboratories offered staff education and agreed that PT can be a valuable educational tool, using it with employees and with students. Many participants from all types of laboratories liked using PT to support staff knowledge updates. One participant found PT to be a valuable resource in presentations designed to offer employees the opportunity to develop critical thinking skills.

Laboratorians in some facilities both large and small noted that fear of failure when performing PT testing is a valid concern, since staff is held accountable for the results and the consequences of failure can be serious. Laboratorians at the management level in POLs and in point of care settings shoulder much of the responsibility for *“getting it right,” “getting that 100% grade,”* and they report higher stress levels over PT than bench laboratorians. PT could become a staff motivator when used to educate, *“using PT as a teaching moment,“* on the importance of PT and the value of building a team effort in which they all feel ownership for the PT process as well as its success.

2. Testing Process Improvement

Almost every participant across all groups agreed on the value of PT testing in quality evaluation and improvement of the testing process, although they stated its value in pre- and post-analytical phases of testing was more limited. Larger facilities reported that PT testing was performed on all work shifts to ensure accuracy of sample processing, analyzing and reporting.

Many participants noted that use of PT in pre-analytical phases is often limited to ensuring proper labeling since PT samples must be handled differently from patient samples. There are different protocols for entering PT samples into the system, and the samples themselves must frequently be processed differently. The value of PT in post-analytical processes is also limited often having the potential for creating more transcription errors based on how differently PT samples must be managed in laboratory systems. Therefore, most expressed the greatest value of PT was in the analytical phase.

3. PT Use to Assess Methodology/Instrumentation

Most participants valued PT highly in technical and analytical circumstances in which PT material is used to test the accuracy of various systems, validate new instrumentation, verify accuracy with user-developed tests and troubleshoot analyzers. One challenge in the larger laboratories when the same test is performed on multiple analyzers is that determinations must be made as to which analyzers should be designated for analysis and for reporting of each PT analyte. The tracking and documentation of various instruments used results in additional paperwork.

Most participants also mentioned using PT summary reports to obtain additional information to change or recommend changes in methodologies or instruments and they often choose vendors based on their PT performance, noting that they would check standard deviation (SD) and coefficient of variation (CV) for accuracy and validity of testing results. Some small laboratory participants reported that they would not use PT summary reports to change methodologies since they felt that PT results can differ even if calibration and quality control (QC) values are the same; however, they would use PT summary reports to compare instruments if there is interest in changing instruments.

Almost all stated that they would check peer information to confirm that the number of laboratories enrolled in their program using the new instrument or methodology is sufficient to allow the PT program to provide a grade and to offer peer comparisons. Also, most use PT peer comparisons from summary reports to identify which methodologies most people are using and how many laboratories are using a particular analyzer with a particular PT program. They report that they can use it as justification with upper management for changing methods or instruments. One participant remarked that "...if, over time, you notice that a lower number of laboratories are using the method or instrument you are currently using in the PT program in which you are enrolled, that can be an indicator of the need to make the change."

4. PT Value in Trending

Most confirmed that they used PT results to monitor trends in results. If over time a PT result is still in range but has moved significantly in one direction (e.g., starting below the mean in one challenge, moving up to the mean in the next and above the mean in the third challenge), that trend could be used to identify a problem before it becomes significant.

Several respondents from small facilities reported trending less frequently because they felt that the individual PT analyte samples vary a great deal from one survey to another. When there are PT results in ranges that are at the extreme high and low ends of the analytical range, they found the data less useful for methodology and instrument monitoring.

Many participants from the microbiology groups reported that trending is not useful in microbiology laboratories because organisms in PT samples are not repeated on a frequent basis; it is not feasible to identify trends. Where the chemistry laboratory would have several opportunities to measure the same analyte over the course of a year, the microbiology laboratory might not have the repeat opportunity for several years.

5. Assuring Assay Accuracy without Commercial PT

To meet the CLIA requirement of verifying accuracy twice per year when there is no CMS-approved PT program available, most participants would assure that an assay is working properly by sending the sample to a reference laboratory, performing an in-house procedure using blinded samples and previous known samples with two different laboratorians or exchanging split samples with other laboratories. Several participants suggested that there must be a balance between the cost of a single survey containing multiple analytes to cover the one analyte that you require and the cost of developing in-house PT or using a reference laboratory for that analyte. One respondent from a small laboratory noted that it is sometimes cheaper to send six split samples twice a year to a reference laboratory than to pay for the PT program, especially if there is concern with the PT program grading and they feel that their laboratory is achieving accurate results. Most would like more guidance when PT is not available.

Several participants in microbiology laboratories indicated that if they perform patient testing for which PT is not available, they perform an in-house PT. One example of an in-house PT was setting up a program twice a year in which five laboratorians examine the sample and separately record results with a referee then reviewing the results (e.g., wet mounts and KOH preparations).

When asked if they would opt not to use an available commercial PT program to verify accuracy for analytes not required by regulation, almost every participant across all groups replied that they would opt to use commercial PT if it were available since it would be much easier and probably cheaper than developing their own PT provided the quality was consistent. However, most also agreed that that it is important to ensure that a PT sample closely resembles a patient specimen. Smaller laboratories, especially the POLs, did not address this alternative, as they do not perform patient testing for analytes other than those for which PT is required under CLIA.

C. PT Benefits and Challenges

1. Benefits

As previously reported, participants repeatedly stated that the most important benefit of PT was increased confidence in the quality of a laboratory's performance along with its value as a quality indicator for stakeholders at various levels, with staff competencies, peer group comparisons and educational opportunities a close second. Most participants agreed that the benefits of PT outweigh the amount of staff time required to do PT and valued the many additional uses of PT. In addition, they noted that PT was also valuable as a quality indicator that supported their laboratory credibility and justified PT laboratory costs with stakeholders such as hospital board members, administrators and clinicians. In addition, assuring staff competency, building knowledge through education, providing peer group comparisons and PT trending were rated as extremely important benefits of PT. Many laboratorians use PT materials such as slides and photomicrographs as ongoing training resources. Leftover PT material is used for teaching, verification of results, and maintaining stock cultures of organisms.

2. Technical Challenges

While some technical challenges in PT were specific to individual facilities and there were many minor technical challenges noted, the most common technical challenges that these laboratorians considered troublesome included:

a. PT Sample Unavailability
b. Matrix Effect
c. Ungraded PT Challenges
d. Advances in Technology

a. PT Sample Unavailability

The analytes for which commercial PT is unavailable create considerable difficulties mainly for large laboratories, since they view developing alternate PT a significant challenge. Large laboratories reported that platelet aggregation, leukocyte alkaline phosphatase (LAP), staining for Heinz bodies and some molecular tests have no commercial PT. In addition, PHL participants listed tests for hantavirus, Q fever, microsporidium and cyclospora as having no commercial PT.

Because PT programs do not always respond quickly to the emergence of new technology with updated PT availability, larger laboratories that acquire updated instruments or methodologies not yet addressed by their PT programs or those that perform environmental analysis or testing for drugs of abuse are often faced with the unavailability of commercial PT samples appropriate for the new instruments or methodologies. Although not covered under CLIA, several PHL participants still expressed frustration with the lack of availability of commercial PT for environmental tests. Another respondent noted that in forensics laboratories there are always analytes (e.g., new drugs of abuse) for which there is no commercial PT, as there is a two to three year lag time from their appearance in the population to the generation of PT samples for those new analytes.

b. Matrix Effect

In PT samples, the matrix (the substance in which the analyte is embedded), may be very dissimilar to that of patient specimens. Matrix effect, the combined effect of all components of the sample other than the analyte on the measurement of the analyte, may influence the way the sample is processed, how the analysis is conducted and the quality of the results obtained.

Many from large laboratories agreed that the frequency of samples with a substantial matrix effect could be problematic. Microbiology and PHL participants viewed matrix problems as occasional, and small laboratories did not consider it a significant problem as long as they "stayed within the guidelines and ran the test following the instructions it would not be an issue, but the sample does NOT behave the same," which means that they cannot treat the sample as a patient.

Large laboratories retest an outlier, and if the result is still the same they call the PT program to determine if the nature of the matrix for that analyte requires special handling of the sample. One example cited was that of urine PT samples that, when processed and analyzed as patient samples, produce incorrect results.

c. Ungraded PT Challenges

A majority of respondents across all groups reported that ungraded challenges due to lack of referee consensus happened infrequently, and most seemed aware that corrective action is necessary even if the challenge is ungraded. Most use detailed procedures to review and compare their results to those of other laboratories testing the sample. If a response is not consistent, corrective action is performed and is clearly documented. One PHL participant indicated that his laboratory belongs to a network of four laboratories that trade samples of ungraded challenges with each other for results verification after finding that a challenge was ungraded. A few participants replied that if the test could be rerun for an ungraded analyte, they would send samples to other facilities to determine if their results match. One respondent observed that when a PT challenge is ungraded, it is often a sample problem.

Several others suggested that pre-identified ungraded challenges can be viewed as educational opportunities, while another respondent added that there are also separate educational challenges that are ungraded but they are usually in paper format and do not involve a sample.

d. Advances in Technology

Some of the larger laboratories, including the PHLs, were concerned with what they perceive as the "lagging behind" of PT programs in not acknowledging the latest sophisticated instrumentation and methodologies. This sometimes results in laboratories with updated instruments or methodologies not being able to get commercially prepared PT samples or in samples behaving differently on instrumentation or methodologies not yet recognized by the PT programs. For example, detection limits on a new instrument that are lower than the detection limits of other older instruments may result in a positive PT sample value for that new

instrument and a negative PT sample value for the older instruments still in place in most participating laboratories.

Miscellaneous comments on technical challenges also included an observation that grading can be unfair when compared to others using different methodologies and/or instruments.

3. Administrative Challenges

The top two administrative concerns voiced by every participant were the high cost of PT programs and the increased amount of staff time required at all stages in the PT testing and reporting process. Despite these concerns, while those in upper management dislike the high cost of PT, they do not resist paying for it as the requirements for PT are clearly documented.

a. PT Program Costs
b. Staff Time

a. PT Program Costs

When asked, most participants across all groups agreed that the expense of PT can be difficult to justify in the budget. Others detailed experiences with having to buy multiple modules to cover all analytes tested for in their laboratory, compared to investing in a single module that covers multiple analytes just to include one analyte that is not covered elsewhere. Several suggested that costs can be lowered by finding the correct configuration of modules to meet one's needs rather than purchasing too many unneeded modules, but stated that it requires extensive research.

One large laboratory respondent summarized the group's feelings by saying "the biggest challenge is finding the right analytes at the right time in the right matrix at the right price." Regardless of its impact on the overall budget, all agreed that PT is required and must be performed. The cost can be justified for CLIA-regulated analytes because these must be purchased from CMS-approved programs. However, many feel it is a financial burden and would like to find ways to lower cost.

Several participants expressed annoyance at having to pay for PT when samples are not graded because of lack of consensus (even though this happens infrequently). They felt that there should be more quality control of sample development on the manufacturing end.

One POL participant commented that, in the grand scheme of things, cost is not a controllable factor if it is required for being able to perform a test in-house; "You pay whatever you must to stay in compliance. If you don't run PT for every regulated analyte, you can no longer run a test that is generating revenue. You could spend more in one week on a test that you cannot be reimbursed for than you would spend on PT for that analyte in a year."

Most agreed that while upper management would like to pay less than they currently do for PT, they accept that performing PT is part of complying with regulations. Since there is no reimbursement if the laboratory is not in compliance, revenue is lost if the laboratory cannot perform the test. "Everything goes away if PT is not in compliance. They care about where the

money is going, but they are resigned to the cost because the alternatives are not acceptable. They see, understand, cooperate, but complain…" One participant did state that in her facility PT is a high priority for upper management, and a majority of respondents agreed that management understands the importance of quality and is reluctantly willing to pay for evidence of that quality through PT.

A POL respondent noted that, although the laboratory checks quality at all parts of the process, they still could be performing costly procedures not regularly done just to confirm that a PT analysis is achieving correct results. For example, a patient specimen with an extremely high value considered incompatible with life would be rejected, per normal laboratory protocol, as an unacceptable specimen and a redraw would immediately be requested. Since PT programs do not offer that option, costly repeats and additional testing is done, even though the instructions are to treat the PT sample as you would a patient specimen.

b. Staff Time

Most participants across all groups agreed that PT is time consuming and sometimes difficult to build into the workload since PT challenges are often set up differently than patient specimens. In microbiology, some felt that the burden on staff time is high and that it is difficult to find time in the normal workday for completing and reporting PT. Paperwork, time reporting and tracking staff to ensure that everybody does PT at least once in a cycle also can be an issue. Large laboratories also have difficulty including staff from all three shifts in PT testing especially with PT samples that are labile.

Others did not see staff time for the actual testing as a problem since it is incorporated into the workday and the daily runs, although some felt it was more difficult to adjust workloads when all the PT samples are delivered at the same time. Some microbiology laboratories reported that they work around time issues by using discretion on when to begin PT with a Friday arrival being held for processing until a Monday.

In a few of the small facilities, participants noted that because additional tech time is needed for result reporting, PT testing can take time away from routine testing when they are already short-staffed and it is possible to short-change patients if personnel are rushing through routine testing to get PT done.

Almost all participants expressed frustration with the time required for documenting the ordering of PT in the laboratory system, reporting requirements that vary from various PT programs, the extensive network of internal approvers required, the labor required in the tedious process of paperwork volume, and ensuring of clerical accuracy with review for transcription errors. Even if PT samples are handled electronically, the laboratory information system must handle the data separately and the opportunity for transcription error rises. They also noted that the reporting mechanism for PT requires additional staff time and is not the same as for reporting patient results.

Most PHL respondents believed that analyte grouping for normal PHL testing algorithms affects staffing and staff time. Some PT requires efforts from multiple staff teams, and this

time constraint on staff can be challenging. For example, if a PT sample must be completed by different divisions, it can become very time consuming to coordinate access by the divisions/departments so that they can get their individual assays completed.

Several participants pointed out that while laboratorians may become more complacent with their daily testing, PT samples are treated differently with testing personnel taking more time and paying closer attention to PT samples. Many cited frustration with the staff time needed to maintain anonymity since even with creative ideas such as pretending the sample came from a reference laboratory or creating fictitious laboratory identification numbers, the PT sample still cannot be treated as a patient specimen. Consequently, PT takes more staff time.

Small laboratory respondents observed that scheduling and managing their time to do PT testing is stressful, but most agreed that the stress is worth it because, as one POL respondent stated, “We want that 100% grade to show the clinicians the high quality of our work.”

D. PT Program Satisfaction

When participants were asked about their satisfaction with their PT programs, their responses varied. Satisfaction responses fell into two broad categories: technical issues and provider services.

1. Technical Issues

Many expressed frustration with the fact that most of the technical issues were beyond their control and could only be remedied if the PT programs addressed these technical improvements as a customer satisfaction measure. They viewed individual feedback as not very powerful and several commented, “we just work with what we have.” The most common technical topics for which they expressed that frustration included:

a. PT Sample Quality/Quantity
b. Unit Consistency
c. Report Format/Interpretation

a. PT Sample Quality/Quantity

Satisfaction with quality and quantity of the PT samples was mixed and included recommendations for improvement of poorly stained slides and distorted images in pictures and photomicrographs in microbiology and hematology. The quantity in an individual sample was sometimes not enough for a repeat before reporting and usually not adequate for retesting at a later date. Some samples require complex reconstitution instructions to achieve the correct consistency before analysis can be performed, and so many would prefer to receive samples ready to be analyzed without reconstitution since this step is an additional source for error that is not present in the patient specimen.

Problems noted with other types of PT samples that do not need reconstitution included the difficulty in measuring blood gases without adjusting the analyzer to accommodate the PT

sample and the inability to preserve hematology samples to be rerun as part of the corrective action even if an erroneous result was reported. Even if a sample such as a chemistry sample could be frozen, the sample often contained insufficient quantity for reruns.

In microbiology, both quality and quantity have been an issue. One participant highlighted the difficulty in determining the sample source. Most agreed that the quality of slides is poor in bacteriology and parasitology, particularly Gram stained slides. Most agreed that sample pictures and photomicrographs need improvement. Image quality and size may be distorted, although it was their opinion that pictures cannot always test proficiency. Several felt that the parasitology PT survey in particular could use overall improvement, but no suggestions were offered.

Many of the microbiology respondents observed that while a patient specimen would be handled by viewing multiple fields before reporting, PT sample identification relies on one, sometimes slightly out of focus, usually one-dimensional photomicrograph image. It is difficult to identify something from one photomicrograph since it is not possible to focus on the images; even if the images are available online, they can be difficult to access due to high system security. Most questioned the value of identifying any entity by one photomicrograph or one slide field, with no other pertinent information, which is not consistent with how they would approach identification in the laboratory.

Opinions on the quantity of PT samples were mixed (from adequate to inadequate) in all groups but concerns increased regarding low sample volume (e.g., one swab for stool PT testing,) when a laboratory is unable to repeat tests, especially for corrective action due to depletion of the sample on initial testing. Some participants stated that the consequences of poor quality or insufficient quantity can be incorrect or unusable results. The penalties for "being out" can be high, yet even when it appears that there is a problem with the sample, "PT programs don't admit their errors and don't cut you much slack." Most did agree that if an unacceptable sample is reported within the specified time frame, the PT program will replace it and if the program is unable to provide a new sample the laboratory is not graded on that challenge.

b. PT Reporting Unit Consistency

While most microbiology laboratory respondents agreed that PT units are consistent, almost all other laboratories reported problems with unit consistency. One small laboratory respondent observed that PT samples must be reported in units that are different from those used to report patient results, which causes the need for extra attention to be paid to unit conversion for reporting PT results. Another participant reported the inability to use greater-than or less-than symbols if the result is outside of the linear range for their instrument because the use of such symbols is not accepted by the PT program. A few observed that a change in reporting units required by the PT program had occurred with no notice to enrollees until incorrect results prompted inquiry by several laboratories.

c. PT Reporting Format

Most participants across all groups were satisfied with the reporting format of the PT program in which they were enrolled. Several cited confusion with different reporting formats when using more than one PT program. One respondent mentioned that the process of reporting PT results is different from how the facility reports patient results. Another commented that forensic and toxicology laboratories normally report patient results with cut-off points, which is different from how they are expected to report PT results. In addition, because every calibration scale is different, the laboratory must use the templates provided by the PT program to do corrective action.

2. Non-Technical Issues

Responses on satisfaction with PT program services also varied. Most were satisfied with the technical feedback and advice received from program experts, but many were frustrated with their PT program customer support and expert access.

Non-technical topics explored included:

a. Technical Advice/Feedback
b. Customer Service
c. Peer Grouping/Comparisons
d. Subscriber and PT Program Turnaround Times (TAT) and Reporting
e. PT Program Problem Solving

a. Technical Advice/Feedback

Most respondents were satisfied with the technical feedback and advice received from the PT program experts when they contacted them with a question or concern. It was noted that, when communicating with PT programs, the "quality of feedback can depend on the reputation of your laboratory, who you know and the rapport you have established, how persistent you are and what compelling factual information you bring to the table." Most agreed that PT programs are prompt in responding to technical inquiries submitted via email. It is important to remember most consider the information in the results thorough and were satisfied with the summary reports. In addition, several mentioned that PT program websites provide additional information beyond what is given in the reports. It is important to remember that the key with consultation for technical advice or other issues is to document the conversation.

b. Customer Service

Many were frustrated with their PT program's automated telephone response system of number selections, preferring to speak to a person who can direct their call based on their specific need. Some also were frustrated because the customer support employee speaks from a script or list of instructions about policy and procedure, rather than transferring the caller to a technical expert. Some respondents stated "they need a technical expert

the minute they get a live person on the line." When the technical expert, who "speaks the language" responds, they are usually satisfied and the problem is quickly resolved.

Microbiology respondents remarked that they did not wait long on the telephone despite the fact that they do not always know which prompts to choose. Most microbiology group participants also agreed that experts are prompt in responses and provide satisfactory answers, and that if a technical expert does not know the answer, the caller is immediately referred to someone who is more expert. In fact, they were impressed by the specialized expertise of PT program microbiology experts.

c. Peer Grouping/Comparisons

Several participants spoke to the value of peer grouping for interpreting results with many agreeing that they use peer grouping to see where their results fall among their peers, how many others use certain methods and for instrument comparisons. A few did suggest that it would be helpful if those groups were broken down by facility size and types of testing technology used in the facility.

d. Subscriber/PT Program Turnaround Times (TAT) and Reporting Methods

Almost all respondents agreed that the turnaround time from receipt of the PT sample to submission of testing results to the PT program allows sufficient time for analysis. Most participants preferred to receive the final critique more quickly and felt that electronic results and reports posting reduced this time for those with computer access. Most viewed the turnaround time from results submission to receipt of a grade as adequate, with the exception of microbiology respondents who believed that the grading of mycology results is especially slow. Several respondents felt that the current turnaround time is acceptable but noted that it is too long if rerun of labile samples is necessary and that it means that at least a month has passed before they are aware of the need for corrective action and staff remediation.

With many PT programs moving to electronic results and reports posting, most respondents agreed that they preferred to receive results in electronic format. Most participants stated that it is helpful when PT programs send electronic links because it reduces the time required to get results. However, one participant from a small laboratory felt that options to receive results by mail were necessary for those without regular computer access.

e. PT Program Problem Solving

Responses were mixed on the ways and degree to which PT programs respond to complaints and addressing problems demonstrated by PT programs. A few participants were satisfied by their PT program's response, but many others viewed PT programs as not practical and too rigid in dealing with complex, individual circumstances. A respondent from a small laboratory noted that "PT programs sometimes don't exercise common sense." A common view was that PT programs often will not admit when a PT problem is the result of their error, and those enrolled in the program must wait until the next PT cycle for resolution. In one specific

instance, incorrect results, submitted only because the PT program changed reporting units without notification, were not allowed to be corrected. The laboratory was graded, failed the PT event, and had to wait until the next PT cycle to fix a simple unit conversion issue when it could have been part of a corrective action. Inflexibility of a PT program that requires purchase of an entire panel when a laboratory only tests one or two analytes in that panel caused one laboratory to change PT programs in order to reduce unnecessary costs.

E. Microbiology-Specific Topics

In addition to the general discussion on use and perception of PT testing that have been described previously, the two microbiology focus groups and the PHL focus group were asked several additional questions on microbiology-specific topics:

1. PT Background/Patient History Information
2. PT Reporting Consistency
3. Reference Laboratory Utilization
4. Individual PT Analyte/Test Scores
5. Increasing Microbiology PT Samples/Challenges

1. PT Background/Patient History Information

Microbiology-specific responses indicated that most participants felt that the background information received with a PT microbiology sample is comparable to the information received for a patient specimen. There were some participants who preferred to receive more information than is currently given, citing the need to at least have age and sex provided to enter the samples as patient specimens in their systems.

Several participants expressed disappointment that laboratories do not receive much information with Bioterrorism (BT) PT samples, but another respondent commented that, with BT, “the source of the sample may be all that you have in a real event.” After general discussion, most agreed that it was valuable to monitor the timing of processing, resulting and reporting a BT PT sample since short turnaround time would be desirable for a potential BT event.

2. PT Reporting Consistency

When asked how they assured that the reporting of results for PT of organism identification is consistent with the level of reporting for that organism in their laboratories, (e.g., species level, genus level, Gram stain only), most reported that PT instructions require that PT results be reported to the same level as would be reported for patient testing. For many, workflow mirrors patient sample procedures, but for those that did not routinely report at the level requested, they would comply with instructions and report at the level requested even if it is not the level that they would report a patient result. One participant mentioned that in her state (NY) all laboratories must complete a survey confirming the level of reporting for every organism tested in their laboratory which makes PT grading more fair.

3. Reference Laboratory Utilization

Participants stated that they would not send PT samples to a reference laboratory. Some mentioned that their written laboratory protocol for patient specimens may include referral of at least a portion of the testing to a reference laboratory under certain circumstances, but that they are unable to follow this protocol with a PT sample. This causes frustration for some laboratories.

4. Individual PT Analyte/Test Scores

Having an individual score for each testing procedure in addition to the combined microbiology score on PT samples would be welcomed by the PHL and both microbiology groups. Separate scores could identify which areas of testing and staff skill should be targeted and make trending easier to manage where trending is practical. In all three groups, most agreed that the combined subspecialty score makes it more difficult to fine-tune the improvement of accuracy, level of specificity and staff skill levels. It would be more useful to separate out scores so that training can be focused on specific testing procedures that have consistently lower or unacceptable scores.

5. Increasing PT Samples/Challenges

When asked what additional burden an increase in PT for a particular method or organism would cause, responses were mixed. Several supported having more susceptibility tests and felt that if susceptibility challenges were increased that laboratories would have more confidence in their patient results. One participant felt that there is no benefit to a quantity increase in PT, but an increase in the frequency of challenging tests would be beneficial. Another felt that there should be more testing for specimens received and run more frequently in your laboratory. One or two participants stated that detection of organisms that often appear in low numbers in a mixed culture, as seen in patient specimens, would be a useful exercise. A few respondents would resist performing additional PT since more time is already devoted to testing PT samples than a normal patient specimen. At least one laboratory also performed PT required by their state and viewed additional PT testing as an additional inconvenience.

6. Miscellaneous Microbiology Comments

Most microbiology respondents view the PT samples as an important source of stock cultures for organisms that may not be seen often. One participant remarked that it is important for laboratories to practice identifying samples containing organisms that are seldom encountered, while another stated that in one instance an infrequently occurring organism in a PT sample prompted the laboratory to develop additional testing protocols.

Some microbiology respondents have encountered difficulties with antimicrobial susceptibility samples, since the results can be affected by the number of passes for the organism being tested. They agreed that this is a significant problem because a laboratory could be ungraded or receive an incorrect answer based on the nature of the PT sample, not the quality of the laboratory analysis.

A few microbiology participants felt that the control values for molecular tests accurately reflect patient ranges but that the PT sample values for molecular analytes do not accurately reflect those ranges. Several participants reported little unit consistency among manufacturers with only a few assays (e.g., Hepatitis B) having an international standard.

IV. RECOMMENDATIONS FOR IMPROVEMENT

Most recommendations for improvement closely paralleled participants' accounts of current challenges in performing PT. While they value PT as an integral part of their laboratory quality programs, they do see room for practical improvement. Overall suggestions covered several categories, including:

A. PT Cost
B. Samples/PT Modules
C. PT Reporting
D. General Recommendations
E. Microbiology-specific Recommendations

A. PT Cost

All participants agreed that a high priority need was addressing the high cost of doing PT and that more viable competition for subscribers among the PT programs could ease cost issues for some facilities. If cost reduction is not possible, many laboratorians have identified additional ways to use PT in their facilities to help justify the investment.

Overall, focus group participants would like to see more customized modules and service from their PT programs. Most would like some way to select analytes from a menu and be charged by the analyte. Many would like to have menu options to add individual analytes not included in their main PT package to avoid having to purchase a separate module that includes those analytes. One participant commented that the laboratory may need only one or two analytes in a panel but must pay for the entire panel that contains the one or two that they must run. Another felt that it would be beneficial if PT program experts were able to work with clients to recommend appropriate PT surveys that are better fits for their laboratory's needs.

B. Samples/PT Modules

Most focus group participants would prefer to have more comprehensive modules instead of multiple smaller modules, with the exception of microbiology participants who expressed a preference for a more staggered arrival schedule for samples.

All participants would prefer more stable PT samples that more closely resemble patient specimens, both in appearance and in results, and would prefer to test for more unusual analytes or low positive values in PT samples than report out negative results. Values at the low or high end of a range would be expected to occasionally occur in patient specimens. There is a perception that some PT samples are outside of this range, most likely due to the normal population of that particular laboratory.

Although a laboratory's established protocols may require patient specimen rejection and redraw when testing results are not within a designated range, the laboratory is not allowed to follow its protocol for repeat of or request of new patient specimens with PT samples.

Several expressed dismay with what they consider the excessive number of negative samples, noting that the high cost of PT tests should warrant more testing for the ability to identify positive samples (e.g., presence of unusual antibodies, presence of a seldom-encountered parasite) and low positives, especially when these values mirror possible patient results. Most felt the ability to detect the presence of an analyte, even in low amounts, was more critical for demonstrating competency than establishing the absence of an analyte in a PT sample.

A few respondents noted that PT programs should be aware of the newer instrumentation and methodologies that may be used in the laboratories enrolled in their programs to assure that those who use the newer methodologies are not penalized.

C. PT Reporting

Most participants would like to reduce paperwork associated with reporting their PT results. Extended reporting surveys can be confusing and difficult to complete, as not all aspects of the survey are applicable and it is too easy to miss checking off an item or an option. Participants felt that it would also be more efficient to have consistent streamlined formats from one PT panel to another since reporting requirements are so different among the PT panels. Participants recommended having all PT reporting on one standardized form. Several suggested that it would be helpful if the PT programs could work together to determine a uniform set of reporting units and matrices.

Most agreed that electronic reporting is beneficial and prefer to receive their PT summary reports via email rather than regular mail. Several remarked that some of the PT program websites to retrieve PT results are not user-friendly. Laboratorians must download a PDF file and print the document while they would prefer to print by clicking on the document directly.

D. General Recommendations

Multi-site facilities recommended that there be more flexibility to accommodate a laboratory's usual testing protocols. For example, multiple location clinics sometimes consult a pathologist who may not be physically on-site at the time, per normal laboratory protocol, but consultation with a pathologist who is not on-site is not allowed by CLIA.

Several participants enthusiastically recommended that PT be used in industry marketing. For example, if a representative sells reagents or an instrument to a laboratory, that representative could recommend a PT program for that instrument based on the number of laboratories enrolled in that program that are currently using the instrument. The instrument manufacturing company representative could then show prospective buyers a good track record with that PT program for that instrument as a selling point. The benefit for laboratories is that they would also know that they are selecting a PT program that has a sufficient number of laboratories enrolled for the analytes they test and the instruments they use.

Small facility participants would like to see more delineated and regimented instructions for minimally qualified staff. A summary of the PT results in addition to the individual results and peer information would be helpful. One POL manager noted that "some of the things that happen to others may not happen to me and so I am not aware of an issue that may help me to avoid a problem in the future." Since some laboratories do not want electronic instructions, they suggested that the PT programs offer an option to get instructions as a printout from an online source.

PHLs would like to have those hospital-based laboratories participating in the Laboratory Response Network (LRN) also participate in LRN-specific PT. They also felt that sentinel laboratory participation should be approached cautiously since it takes considerable time and effort for the PHLs to develop a good relationship with a sentinel laboratory. Some respondents suggested that PHLs could recommend sentinel laboratory participation from a patient safety-related issue, as some sentinel laboratory safety lapses have already been detected by the PHLs. A practical approach may be to consider having PHLs send out LRN-specific PT samples that include packaging and shipping competency assessments, to the sentinel laboratories. Most PHLs also agreed that adding turnaround time for LRN PT samples as a measure of competency was valuable, but acknowledged that it may become too complex to accomplish within the PT program framework.

E. Microbiology-Specific Recommendations

Most participants would welcome the challenge of more complex organism samples and fewer negative samples. Many would prefer to see PT programs do a better job of scheduling their PT shipments to relieve time constraints that are sometimes overwhelming for staff. Taking into account the frequency of staff vacations in December and other holiday times would also help in workload distribution.

Many in one microbiology group requested some resolution to the discrepancy for certain organisms between Clinical and Laboratory Standards Institute (CLSI) and FDA breakpoint values, where FDA breakpoint values are higher than those of CLSI.

V. LIMITATIONS

The small laboratory group had a lower participation rate than the other three groups. A reason may have been revealed in project recruiter observations during small facility/POL recruitment. For the locations in which small facility focus groups were scheduled, it was difficult, especially when contacting POLs, to speak to those actually performing the testing. Several of these facilities told the recruiter that they were short-staffed, sometimes with one person attending patients, performing laboratory testing and managing the office; and so, the recruiter's inquiry was considered low on their list of priorities. In one location, severe weather adversely impacted the number of already confirmed attendees.

Recruiters observed that in small facilities in which laboratory tests are performed by nurses or medical assistants with less formal background in laboratory testing and PT, there was little or no interest in participation in the focus groups. In those facilities where tests were performed by clinical laboratory personnel, CLS/CLT (or MT/MLT), interest in participation was higher.

VI. POTENTIAL FUTURE ACTIVITIES

While discussions focused on the major issues surrounding PT, the commitment of the majority of participants for quality laboratory testing offers some opportunities for future activities related to PT. These potential activities include:

- Exploring the educational PT needs of those at the management level, individuals with little laboratory or PT experience, and other health professionals involved with laboratory PT;
- Enhancing awareness of the value of PT with training sessions developed for physician office and other small laboratories to assist them in addressing unique challenges that they may experience with PT;
- Developing innovative training sessions and guidelines to help supervisory staff effectively use PT to assure regulatory compliance and improve quality in their laboratories;
- Developing, distributing and analyzing a larger nationwide survey based on the key themes and topics represented in these focus group findings to broaden the findings of this study; and
- Comparing how health professionals who are not laboratorians but who are performing laboratory testing may use and perceive proficiency testing differently from a traditional laboratory professional.

VII. SUMMARY

Regardless of facility size or specialty, the most important benefit of PT shared by the majority of participants was increased confidence in the quality of a laboratory's performance along with its value as a quality indicator for stakeholders at various levels, with staff competencies, peer group comparisons, evaluation of new methods and technology, and educational opportunities close behind in importance. Many laboratories use PT materials such as slides and photomicrographs as ongoing training resources, and leftover PT materials are used for verification of results and maintaining stock cultures of organisms and other cellular elements.

While there were many instances in which the perception and the use of PT were similar for all groups, issues from large facilities, microbiology departments and PHLs mainly focused on overall PT program requirements and services. They were more able to absorb the additional time required for testing and documentation by distributing the work among several laboratorians or departments. They viewed PT as an opportunity to expand and improve at both personnel and institutional levels.

The smaller facilities tended to focus more on meeting the PT requirements for testing accuracy and fitting PT analysis and paperwork into the staff schedule without jeopardizing patient testing. Meeting the requirements of PT testing was sometimes seen as an additional strain on the balance they struggled to maintain. While they do value PT as a competency tool and for educational activities, they are not always able to maximize PT opportunities that were described by the larger facilities.

The larger laboratories expressed concerns that PT programs have not kept abreast of newer instruments and methodologies and so were slower to incorporate updated samples and protocols

for newer technologies. There have been instances in which the PT program reported the response for a challenge as “negative” but two laboratories using a newer instrument with a lower detection limit reported positive results and were scored as incorrect. Some small laboratories, especially POLs, expressed frustration with PT program protocols that assume the need for checks and balances that are now automatically performed on some instruments, which do not allow the operator to proceed when the QC values or the calibrations are not within limits.

All participants believe there are opportunities for improvement in PT sample quality and services. The imperfect nature of the process and the frequent shortcomings of sample integrity have led laboratories to discover creative ways to work around many of the challenges of performing PT.

In all facility types, PT is a motivating influence for those laboratorians to excel in their performance. Others are extrinsically motivated by a fear of failure or the consequences of the laboratory loss of accreditation and its implications for their own jobs. For most participants, the quality demonstrated by successful PT is critical for their stakeholders, especially laboratory directors, managers, administrators and the clinicians who depend on their results in patient care.

Perceptions of inflexibility of PT programs in the recognition of the multifaceted conditions under which most laboratories operate and the challenges inherent in treating a non-patient sample as a patient specimen do create high levels of frustration in which these laboratorians sometimes feel that the programs are not focused enough on the goal of proficiency testing, which is assuring quality laboratory testing.

Since they are deeply committed to quality in their laboratories, participants in all groups focused their suggestions for improvement on the practical aspects of integration of PT into their systems and for improvement in the services of the PT programs in which they are enrolled. Overall recommendations were directed toward advantages of PT on laboratory testing personnel and on ideas that were perceived to make PT testing even better able to assure quality laboratory testing.

This project yielded information that begins to explain similarities and differences in laboratory experiences with PT. Overall, these mostly supervisory laboratorians were extremely professional in their responses, committed to the highest quality of laboratory work possible and appropriately concerned about the issues and problems that they believe keep them from doing an optimal job and contributing to continuous improvement in their laboratories.

References

1. Borkan JM. Crystallization-immersion. In: Crabtree B, Miller W, eds. Doing Qualitative Research (2nd Edition). Thousand Oaks CA: Sage Publications. 1999:179-94.

2. Denzin NK, Lincoln YS, ed. Handbook of Qualitative Research. Thousand Oaks CA: Sage Publications 1994: 345-7.

3. Leeber JC. Role of external quality assurance schemes in assessing and improving quality in medical laboratories. Clin Chim Acta. 2001;309(2):173-177.

4. Reilly AA, Salkin IF, McGinnis MR, Gromadzki S, Pasarell L, Kemna M, Higgins N, Salfinger M. Evaluation of mycology laboratory proficiency testing. J Clin Microbiol. 1999;37(7): 2297-2305.

5. Tholen DW. Improvements in performance in medical diagnostics tests documented by interlaboratory comparison programs. Accred Qual Assur. 2002;7:146-152.

6. Ehrmeyer SS, Laessig RH. Has compliance with CLIA requirements really improved quality in US clinical laboratories? Clin Chim Acta. 2004;346(1):37-43.

APPENDIX A: CLMA Survey Questionnaire

APHL Survey on Proficiency Testing in Laboratories

1. Approximately, how many tests are performed annually in your facility? _____

2. If a hospital, number of beds? _____

3. Which of these do you see as a benefit from performing PT? Check all that apply

   _____ a. Regular, external check on quality of testing

   _____ b. Motivation to improve performance

   _____ c. Comparison of performance with that of other participating (peers) sites

   _____ d. Opportunity to obtain feedback and technical advice from programs that offer PT

   _____ e. Way to evaluate methods and instrumentation

   _____ f. Opportunities for staff education/ training

   _____ g. Use in competency evaluation

   _____ h. Opportunities for identifying areas needing improvement

   _____ i. Other/comments

4. What do you see as the most negative impact of performing PT? Check all that apply

   _____ a. Cost of material

   _____ b. Staff time involved

   _____ c. Turnaround time for results

   _____ d. Number of invalid challenges

   _____ e. Unavailable analytes (list which ones)

   _____ f. Other/comments _____

5. Are you confident in interpreting your results from the PT provider? ☐ Yes ☐ No

   a. Why or why not? _____

6. Do you use your PT results to look for trends over time? How is that done and how is it useful? ☐ Yes ☐ No

7. Are you getting enough information back from the provider with the results? ☐ Yes ☐ No

   a. Is peer grouping useful and appropriate for interpreting your results? ☐ Yes ☐ No

   b. What additional information would you like to see? _____

   _____

8. How could PT programs be improved? _____

_____ a. More or less often?

_____ b. More or fewer analytes per challenges

_____ c. More casestudy oriented?

_____ d. Other? _____

9. Do you utilize consultative services from the PT provider? ☐ Yes ☐ No

a. Please describe:_____

_____

10. Why do you perform PT?

_____ a. To meet regulatory requirements

_____ b. To test competency of testing personnel

_____ c. Other? _____

11. Are you familiar with the MMWR articles on Good Laboratory Practice? ☐ Yes ☐ No

a. How do you use this information?_____

_____

If you would like to be entered into the drawing for completing the survey, please complete the following:

Name: _____

Facility: _____

Email: _____

Phone:_____

APPENDIX B: Master Guide Key Questions/Major Probes

Facilitator List: PT Questions/ Major Probes

(Note: highlighted questions are for groups with microbiology departments)

I. How do you use proficiency testing? (appx. 35 min. Start_____End_____)

A. Reasons (other than regulatory)

1. Quality Assurance

- To what extent does PT help you to:
  - Check quality of results?
  - Improve quality of testing?
  - Track accuracy of (testing? results)?
- In what ways do you assure that the reporting on PT samples is consistent with the level of reporting for that organism in your laboratory?
  Example: species level, genus level, Gram stain only…

2. Technical

- In what ways does PT help you to insure proper performance and/or diagnosis problems with the:
  - Instrument/analyzer
  - Sample
  - Environment (such as temperature)
  - Operator
- How can proficiency testing help you to identify /correct problematic assays?
- When PT reports identify problems in testing, what corrective actions do you take (e.g., review of records, training personnel, comparison studies, etc.)?
- Is PT helpful for identifying problems before testing, such as specimen handling, labeling, and aliquoting? *(preanalytical)*
- Is PT helpful for identifying problems after testing, such as transcribing results, calculating dilutions, etc.? *(postanalytical)*
- Is comparison of performance with that of other participating peer sites useful?

3. Instrument Comparison

- To what extent does PT help you to select and purchase instruments and/or test methodology?
- Would PT be valuable as one criterion for changing methods or discontinuing a test from your lab's menu?
- Could it help to persuade management that the cost of that action is justified? Have you used PT this way?

4. Personnel Competency

- Do you use PT in competency evaluation? To what extent is PT useful for testing competency of testing personnel?
- Does it motivate individuals to improve performance?

5. Education/training

- In what ways do you/could you use PT to provide education and training?

6. Reviewing PT results for trends over time

a. Which indicators are reviewed?

b. How is that done?

c. How is review and trending useful?

d. How do those trends influence method, instrumentation and training issues?

e. Does the combined subspecialty score for microbiology PT help or make it more difficult to monitor trends over time? Would it be useful to receive a score for each test or analyte individually in addition to the combined score? (Example: The bacteriology score includes identification, susceptibility testing, antigen tests, and Gram stain is rolled up into an overall combined subspecialty score. Therefore, failures or problems with certain tests may not be readily noticed.)

7. What other ways do you think PT could or should be used?
Miscellaneous: (Defense of values when MDs challenge results?)

B. Benefits (pros) Greatest benefit of performing PT?

C. Challenges (cons)

1. Technical

- Are some analytes you test unavailable from commercial PT programs? Which ones?
- Does this present a problem?

2. Matrix effect

- Does matrix effect present a significant problem in your lab?
- Does it affect how well you can integrate PT samples into your daily run, etc.? *(In PT, since the sample matrix is not always consistent with that of the patient sample, matrix effect (the combined effect of all components of the sample other than the analyte on the measurement of the analyte) may influence the way the sample is processed, how the analysis is conducted and the quality of results obtained.)*

3. Cost

- How does the cost of your PT program affect the overall lab budget?
- Does upper management resist paying for PT unless it is required?

4. Staff/Personnel

- Is the amount of staff time used to perform PT a problem? In what ways?
- What additional burden would be place on your laboratory if there was an increase in PT for a particular method or organism? Example: For all subspecialties, increasing antimicrobial susceptibility testing and/or resistance testing, increasing direct antigen testing.

5. Biggest negative or challenge in performing PT?

II. Satisfaction with service from your PT program?
How could PT programs be improved? (appx. 20 min.) Start_____ End_____)

A. Satisfaction Specifics

1. Sample quality

a. If unacceptable, did it lead to in incorrect or unusable results?

b. Problem identified?

c. How corrected?

d. Matrix effect?

2. Methodology

a. Methods easy to correlate/figure out?

b. Results clear, concise, easy to read, understand, and interpret?

c. Unit consistency?

d. Would requiring PT for generic groups of organisms help you?
Example: gram-negative bacilli, gram-positive bacilli, gram-negative cocci, gram-positive cocci...

3. Results TAT

a. TAT acceptable or not? What IS acceptable?

b. Results received within that acceptable time frame?

c. Received quick enough to help diagnose and correcting problems?

4. Ungraded challenges

a. Definition of ungraded challenges

b. What actions, if any, do you take when you receive results of challenges that are not graded?

c. What do you do to demonstrate proficiency in these cases? What does the evaluation and decision process include?

d. How would ungraded results be reviewed in your lab?

e. Is the number of ungraded challenges you experience problematic?

5. Provider Information

a. Do you feel that you receive adequate background or patient history information for challenges in microbiology? Could be improved in any way?

b. Receive enough information with results?

c. Is feedback and technical advice from programs that offer PT useful?

d. Value of peer grouping for interpreting your results; Is comparison of performance with that of other participating peer sites useful?

e. Consultation with experts at PT program

1. Requests?

2. If requests made, reasons for request?

3. Response to request—helpful or not?

B. Improvement Suggestions?

C. Is there any additional or different information you would like to see?

III. For those assays for which commercial PT is not available, or for which you opt not to use commercial PT, how do you assure that the assay is working properly as required by CLIA? (appx.15 min.) Start_____End_____)

A. Explore if the labs understand what is required by CLIA for demonstration of proficiency. What is done, how often?

B. Amount of time, effort, inconvenience involved?

C. Costs involved?

D. For your assays that don't require commercial PT but for which it is available, why do you opt not to enroll in commercial PT programs?

APPENDIX C: Focus Group Research—Informed Consent for Participation in Discussion Groups

As part of a research study for CDC, APHL is conducting discussion groups to help understand how clinical laboratories perceive and use PT, including whether PT is solely a means to meeting regulatory requirements or if, and how, it adds value that might range from identifying and correcting problematic assays to reassurance that the laboratory is providing accurate testing. We will ask you questions about the benefits you receive from, and your satisfaction with, PT programs, beyond meeting the regulatory requirements. If you decide to join in the discussion, here are some things you should know:

- Your participation is totally voluntary.
- Your name will not be used in any reports about this discussion group. We will be taking notes during the discussion about what was said, but any written reports of the information shared will not identify who made specific comments.
- The discussion will be audiotaped so that when we write our report we can make sure we understand everything that was said.
- You will receive $125.00 to compensate you for your time.
- You may discontinue participation at any time, either by leaving the discussion group or not answering a question, without penalty or loss of benefits.
- Any questions you have about this discussion group and the study will be answered before we begin our discussion. Contact information is provided below for any questions that arise after your participation.
- The discussion group will last approximately 2 hours.
- You will be provided with a copy of this consent form to take with you.

Contact Information: If you have any concerns about your participation in this discussion group or have any questions about the study, please contact Karen Breckenridge at APHL, telephone number 303-617-8827.

Your signature below indicates that you understand the above and agree to participate in this group.

Print your name:_____ Date: _____

Signature: _____ Witness: _____

APPENDIX D: Recruitment Tool

Recruitment tool for the APHL/CDC project. Evaluate the use of proficiency testing by clinical and public health laboratories as part of a quality management system.

Participant Name: _____ Date: _____

Responsibilities: _____

Selecting PT Provider(s) ☐ Yes ☐ No

Filling out the PT results ☐ Yes ☐ No

Reviewing the PT report ☐ Yes ☐ No

Troubleshooting and corrective action ☐ Yes ☐ No

Signing the Attestation statement ☐ Yes ☐ No

Would you be interested in participating in a focus group with other laboratories to look at benefits of participating in proficiency testing? We will discuss your satisfaction with PT programs, talk about the uses for PT in laboratories and successfully incorporating PT in Quality Management programs to improve patient test results.

APHL and CDC will author a report for publication based on the findings from these focus groups. The results of this project will be published for laboratories so they may review peer best practices. The published information may then be reviewed by PT providers.

Would you be available to join a Focus Group (date) _____

at the _____

from ____:00 pm until ____:00 pm?

Light snacks and a $125.00 stipend will be provided. If yes, I need some additional information.

Individual information:

Phone: _____

Email: _____

Facility: _____

Position _____

Years experience _____

Years as supervisor _____

Your specialty _____

Which specialties/sub specialties are performed in your laboratory? _____

_____

Do you do cultures? _____

Which PT program does your laboratory subscribe to? _____

Approximately, how many microbiology tests are performed annually in your facility? _____

Specialty	Sub Specialty	Specialty	Sub specialty
Microbiology		Hematology	
Chemistry		Diag. Immunology	
Immunohematology			
Others			

Contact person for APHL:Morgan Gapara

Email: morgan.gapara@aphl.org

Phone: 240-485-2739

You will need to complete and return a W9 in order to receive a stipend of $125.00. The W9 form will be emailed to you. It may be returned by:

fax: 240-485-2700

email: morgan.gapara@aphl.org

US mail to: Morgan Gapara, APHL

8515 Georgia Ave, Suite 700,

Silver Spring, MD 20910

A reminder email will be sent prior to the focus group meeting to confirm the location and time.

APPENDIX E: On-Site Participant Questionnaire

Focus Group Proficiency Testing in Clinical Laboratories

Today's Date ___/___/_____ (MM/DD/YYYY) # _____

Thank you for agreeing to participate in this evening's focus group. We would like to ask a few questions to learn more about your background and your laboratory.

Demographic Questions

1. Which best describes the laboratory in which you work? (Please select one)

- ☐ Laboratory for a hospital and/or clinic (i.e., centralized laboratory) network
- ☐ University/Medical school/Teaching Hospital
- ☐ Commercial laboratory _____
  - ☐ Single location ☐ Multiple locations
- ☐ Health Department
  - ☐ State ☐ Local ☐ Other
- ☐ Physician's office laboratory
- ☐ Other, please specify _____

2. Does you laboratory provide training for Students from CLS or MLT academic programs?

- ☐ Yes ☐ No

3. Describe your laboratory's certification/accreditation status. (Please check all that apply)

- ☐ College of American Pathologists (CAP)
- ☐ Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- ☐ COLA
- ☐ Center for Medicare and Medicaid Services (CMS)(CLIA COC Laboratory)
- ☐ State accreditation (if applicable)
- ☐ Other _____

Laboratory Personnel Questions

4. How many staff (CLS, technologist, technician, OJT) perform laboratory testing? (Select one)

- ☐ 1-5 FTEs
- ☐ 5-25 FTEs
- ☐ 25-100 FTEs
- ☐ 100 or more FTEs
- ☐ Part time #_____
- ☐ Contract temps #_____

5. Please identify the educational background of your testing personnel (Check all that apply)

- ☐ PhD or MD
- ☐ BA/BS (MT/CLS)
- ☐ MS
- ☐ AA/AS (MLT/CLT)
- ☐ 1-3 yr college
- ☐ High school/GED (on-the-job training)

6. Do you currently have vacancies in these positions? If so, how many?

- ☐ Supervisor #_____
- ☐ Bench level testing personnel #_____
- ☐ Specimen Processing #_____
- ☐ Support staff #_____

Thanks so much for your participation!

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

8515 Georgia Avenue, Suite 700

Silver Spring, MD 20910

Phone: 240.485.2745

Fax: 240.485.2700

Web: www.aphl.org