American Society for Cytotechnology

Statement to the
Clinical Laboratory Improvement Advisory Committee (CLIAC)
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Presented by
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On behalf of the American Society for Cytotechnology (ASCT), representing cytotechnologists, we respectfully request that the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) consider our comments and suggestions for the implementation of a more cost effective, valid, equitable and educational Cytology Proficiency Testing (PT) program. Assuming that the PT program continues, we additionally request that the PT program continue to be conducted on an educational basis and without punitive sanctions through the end of 2006, at a minimum, until comments can be reviewed and the PT regulations re-evaluated.

As a result of recent and ongoing comments collected from our membership, and after an initial request for comments from our organization's Executive Council and Committee Chairpersons, we as a cytotechnologist organization unanimously agree that the PT regulations include some entries which could be retained. These include, but are not limited to maintaining laboratory responsibility for PT enrollment and compliance, continuing the program on glass slide test sets and the testing of non-screening technical supervisors on test sets that have been prescreened. Furthermore, we recognize that changes should also be considered, such as simpler and more equitable scoring criteria, the frequency of testing, the requirement for the size and composition of test sets, the validation process for slides in a test set and the number of retest events allowable as well as the requirement to travel for a retest event. The time period allowable for PT testing also needs to be adjusted. Logistically, larger laboratories need to take extreme measures to ensure many personnel are tested within a small time frame at a facility. The hardship can be alleviated by minimally extending the number of days allowed for the testing event. Overall, the entire PT process and program needs to be revisited and revised to ensure that it is based on the latest and most current scientific and clinical practice guidelines. In making our recommendations, we also acknowledge the need to closely study and ensure that the PT program will not outdate or limit future testing to glass slides only, as technology continues to change. It may even be more cost-effective and equitable to allow choices in program content. Further concern has prompted us to comment and additionally request that the language within the regulation refer specifically to gynecologic testing, thus excluding non-gynecologic specimens from proficiency testing.

Since the PT regulation was established in 1992, there have been cytology related scientific and technological advances, such as computer-assisted screening, location-guided screening, digital imaging and more, which has made a significant and positive impact on the practice of gynecologic cytology. Additionally, the necessary CLIA guidelines, which provide quality assurance for our nation's cytology laboratories, have been put in place and have proven successful, thus questioning the impact on patient care or increased quality of laboratory service that PT would offer at this time. However, as a PT program is mandated, compliance will be most effective if efforts are made to work

toward improvements in the PT program, which may ultimately benefit both the public and the cytopathology community.

On the issues of which we currently have a membership majority agreement, we support the following regulations:

- That it is the responsibility of the laboratory to ensure that each individual examining cytology preparations is enrolled in an approved program. Emphasis here is twofold-that it remain the laboratory's responsibility AND that testing be for each individual cytotechnologist AND pathologist evaluating cytologic preparations.
- That it is the responsibility of the laboratory to ensure that individuals successfully participate or that individuals who fail a test are retested within the required timeframes.
- That it is the responsibility of the laboratory to take appropriate remedial actions for individuals failing a test event.
- That the testing of non-screening technical supervisors be on test sets that have been prescreened.
- That the program content be on glass slide test sets. Options should be made available however, to those trained in newer technologies or those requesting on-line testing events.

On the issue of Diagnostic Categories, the membership currently narrowly supports the current regulation. However, many responses were also received in support of using three diagnostic categories, such as categories A, B and C/D. This would reflect more accurately the current cytotechnologist practice of interpreting gynecologic specimens as unsatisfactory, negative/normal or "refer to pathologist". Still more responses from member cytotechnologists recommended three categories by omitting the unsatisfactory category and further suggested to eliminate altogether the mandatory inclusion of unsatisfactory specimens in the test sets.

On the issues of which we currently have a membership majority agreement, we do NOT support the following regulations:

- The frequency of testing to be annually.
- The scoring criteria that requires 90% pass score, highly punitive 5, 10 and 15 point deductions for a single discrepancy and a different scoring system for cytotechnologists and pathologists.
- The size (number of challenges) and composition (at least one from each diagnostic category) of the program test sets.
- The referencing of challenges and the validation process for specimen slides in the program test events.
- The number of allowed retest events and the requirement to travel to a PT program provider for any retest event.

On the issues of testing frequency, the regulation establishes annual requirements and the requirements expressed in the law are confusing and contradictory. We believe annual testing is excessive. In reference to cytopathology, we could not find any evidence to support a need to frequently test the skills of an individual whose competence had already been established. Diagnostic skills and knowledge possessed by a cytoprofessional during an initial testing event, which previously passed them as "competent" would unlikely disappear and render the individual "incompetent" one year later. In fact, time and experience will enhance diagnostic skills. A loss of diagnostic ability is unlikely and undocumented so it would be unnecessary to repeat a skills test annually. We recommend the testing event to occur every three years, with many members recommending every three to five years. Given the fact that CLIA already provides regulatory safeguards with respect to Pap tests that are being followed and enforced, we respectfully call into question the need for yearly examinations. For example, CLIA regulations require all laboratories engaging in cytopathology to be federally accredited and inspected every two years. Additionally, recently certified Cytotechnologists are now required by the American Society of Clinical Pathologists (ASCP), which certifies cytotechnologists, to complete CME requirements. Yet other diagnostic safeguards are the 10 percent re-screens of all gynecologic cases interpreted to be negative, correlative and retrospective studies exercised on a regular basis. These important measures already ensure cytotechnologist devotion to quality assurance associated with Pap tests. Given the vast, previously established regulatory oversight in this area, a proficiency test administered to cytotechnologists and pathologists every year would be an excessive endeavor. Thus, in our opinion, a test every third year would be recommended and acceptable over the annual requirement prescribed by CLIA'88.

On the issue of scoring test events, consideration should be given for a more simple and equitable scoring system. The Pap test is a screening test, not a diagnostic test and a less punitive scoring system should reflect this fact. Finding and recognizing abnormal cells is what a screening process does; attempting to render specific, consistent diagnostic interpretations starts defining this as a diagnostic test, which it is not. It is generally believed that the grading criterion used to distinguish between an examination result that is satisfactory and one that is unsatisfactory is outdated and subjective, based on individual lab criteria. The cellularity range should not be a rigid threshold and laboratories generally apply professional judgement to determine which adequacy estimations are best suited for their practices and patients. Some laboratories use a hierarchial review. CLIA does not mandate adequacy criteria for laboratories so it is implied that laboratories do and should have some freedoms in establishing and following their own referenced reporting systems.

Another area of concern to our organization is the difference in the scoring system for cytotechnologists and pathologists. While in theory, cytopathologists should be more competent in diagnosing gynecological specimens than cytotechnologists, the opposite is true in actual practice. Pathologists by virtue of their education and position are considered to be held more responsible and accountable for specimen reporting but cytotechnologists by job description and daily practice are the initial diagnosticians and are most accountable for the initial location, interpretation and marking of representative

cells. The general understanding and even expectation that cytotechnologists are the "premier and essential diagnosticians" is supported by statistics compiled from educational programs offered by the College of American Pathologists which consistently show a higher sensitivity and specificity for cytotechnologist interpretations than those of cytopathologists. Pap smear sign out in practice is an equal, team effort and thus, the scoring system for competency assessment should be equal and not more punitive for one professional based on their position. There should not be different "levels and degrees" of competency on the same diagnostic challenge.

The current scoring scheme is thought to be centered in triage and management guidelines that existed in 1992 and which have changed over the past 13 years. Today, however, colposcopy is the recommended management practice for both LSIL and HSIL. Because of this evolution in treatment, the regulation's grading scheme should not mandate penalties for the inability to distinguish between the two. This thought should also be considered in discussion of the Diagnostic Categories, as it supports the comments from some to have three diagnostic categories, with the LSIL and HSIL comprising one category to reflect current cytotechnologist practice of "refer to pathologist" and current patient management guidelines.

Regarding penalties for participants who fail this examination, the regulation calls for what we believe to be excessive sanctions against participants who fail to achieve the minimum mark of 90 percent for satisfactory performance. If the current grading system remains, a score of 80% is recommended for satisfactory performance. Comments received from New York cytotechnologists state that unsatisfactory performance occurs if more than 2 of 10 cases are missed, with test sets requiring only two diagnostic categories, which seems to us to be far less punitive and more accurately reflect the common work practice of a screening test. Additionally, as competence has already been declared in all individuals, careers should not be decided on a single, short test. The overall operation of the laboratory and the total laboratory process ensures quality in testing…not a single screening event. As quality assurance and quality improvement programs have shown us, screening is one small part of the overall successes that contribute to patient care and safety.

Further changes should include the most important aspect of the proficiency testing program...the validity of the test slides. All cases should be validated by a blinded panel of 3 Cytopathologists. A few comments expressed the importance of including cytotechnologists in the review process, as this reflects current practice of having the cytotechnologist as the initial screeners and evaluators. They would be the best test of locator skills and test slide acceptability. Additionally, we request that the validation process occur on undotted slides with biopsy confimation of all abnormal cases with a 100% consensus.

Another factor that can strongly influence the validity of the overall test is the size of test sets and the composition of the test sets. The number of challenges (glass slides) per testing event was questioned by some as not having the potential to accurately assess competency. While 20 slides/event was recommended as frequently as the 10

slides/event, the problem of time and cost came into question, thus resulting in our hesitance to recommend increasing the size of the test set at this time. Our position will be greatly influenced if the frequency of testing were changed to every three years, thus allowing a more accurate and comprehensive testing event, without adding time and financial burdens.

Regarding the composition of the test sets, the ability to test competency when 4 diagnostic categories are known to be included in a set of 10 comes into question. The test becomes a challenge of "mathematical and statistical skill" and not the diagnostic skill that the testing event should measure. To date, our membership is divided on this issue with some in agreement with the 10 slides/event to include certain numbers of known challenges. Still others desire a 20 slide event with unlimited numbers of each challenge to reflect a true, diagnostic competency challenge.

Referencing of challenges should be mandated and laboratories should have the right to challenge the content and result of specimen slides in a test set. Furthermore, a challenge process should be encouraged to ensure that test slides are appropriate. This will identify slides which should not be used for testing purposes. Comments have been sent that report variability in staining, preservation, diminished numbers of diagnostic cells and cells with indistinct and non-definitive criteria which is subjective to interpretation. Conclusive feedback to the individuals and laboratories on challenges is important. Individuals need to know which results were discrepant and what the reference diagnosis was rather than just getting a score. This would add an educational element to the testing. While on the topic of educational component and in order to remedy the near minority that proclaim the Pathologist needs to demonstrate the ability to correctly classify a case, we suggest an educational element that will require a pathologist to further demonstrate the ability to categorize a case into the correct category and that an educational score can reflect this distinction.

The current regulation on retesting events is confusing as to the number of retesting events that can actually occur. We recommend a limit and propose that only two retesting events (3 total attempts) be allowed. We strongly request that all testing and retesting events be performed at the individual's laboratory and not at the PT facility.

We collectively remain committed to ensuring the highest quality cytology testing for our patients. However, this federally imposed annual proficiency examination as it is now, may not improve quality and has resulted in the unintended consequence of laboratories being forced to cut back on continuing education events and other quality programs which may harm overall quality of patient care. Following is one cytology supervisor's assessment of the cost incurred to her lab during a recent PT event:

Following is one cytology supervisor's assessment of the cost incurred to her lab during a recent PT event ($8640.00). Hourly wages were calculated by the average of that laboratory's total wage and benefit package for the entire laboratory ($38.50 per hour). This facility also has 21 pathologists at different physical locations. Their time is not included in the calculation, however proctors must travel to administer the test.

	Participants	Hours			Totals
Direct Cost to PT Provider:	12		$ 75.00	$ 900.00	
				$ 1,350.00	
					$ 2,250.00
National Meeting for PT Information	1			$ 1,000.00	**$ 1,000.00**
Direct Work Hours			**Per Hour**		
Preparation for PT (79 hours)					
National Teleconference	12	2	$ 38.50	$ 924.00	
CT Prep meetings	12	2	$ 38.50	$ 924.00	
Pathologist Prep meetings	1	2	$ 38.50	$ 77.00	
Mock PT	12	2	$ 38.50	$ 924.00	
Mock Pt Construction	1	5	$ 38.50	$ 192.50	**$ 3,041.50**
Proctor time (37 Hours)					
Proctor Competency Test	5	1	$ 38.50	$ 192.50	
Day of test proctor w/ travel	5	4.2	$ 38.50	$ 808.50	
Proctor Time pre test	2	4	$ 38.50	$ 308.00	
After test	1	3	$ 38.50	$ 115.50	
					$ 1,424.50
Testing Event (24 Hours)	12	2	$ 38.50	$ 924.00	
					$ 924.00
Total Cost					**$ 8,640.00**

The cost of PT easily consumes available educational resources for many laboratories.

As this example illustrates, cost goes well beyond the fees paid to the PT provider. Preparation for the event (79) hours included construction of several mock PT sets and educational meetings with staff to prepare them for PT. Attendance at a national meeting for educational needs pertaining to the PT event was $1000.00.

Five proctors were trained and competency tested. Their time (37 hours) is taken away from the established workflow before, during and after the PT event. In this example travel to multiple sites is required.

Direct costs are not the only PT costs incurred by the laboratory. While just the testing event takes 24 hours from productivity, the PT day is emotionally upsetting and physically disruptive to the established workflow. Work on a PT event day does not get

done, often requiring overtime –another increase in cost. Delays in turn around time and report delivery result in client complaints.

In summary:

The ASCT requests that the proposed proficiency testing program and its implementation be re-evaluated in order to produce a more efficient, equitable, valid, accurate and educational competency assessment of individuals evaluating gynecologic cytology specimens. The areas we see as requiring the most immediate modifications include:

- A simpler and more equitable scoring and grading scheme
- Lengthening the frequency of testing
- Reviewing the requirement for the size and composition of test sets
- Utilizing more stringently validated and monitored slides in a test set
- Specify the number of retest events allowable
- Remove the requirement to travel for a retest event
- Increase the time period allowable for PT testing.

Integration of newer technologies such as computer-assisted and location-guided screening will need to be considered as alternative options to the glass slide program content. The changes recommended in this document address the most immediate technical and scientific concerns with the current implementation of proficiency testing. The ASCT will be submitting a subsequent document following full review of the current memberships concerns and comments with further and more specific recommendations for changes, justifications, and impact.

On behalf on the ASCT and our cytotechnologist members, I would like to thank the committee for this opportunity to comment.