American Society for Cytotechnology

Results of Membership Survey based on Recommendations from CLIAC and PT Workgroup

Presented to CLIAC Sept. 20. 2006
As Public comment
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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 and equitable 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 until consensus and regulatory revisions are achieved.

Following the PT workgroup and CLIAC adopted recommendations in June 2006; the ASCT actively solicited its cytotechnologist membership regarding positions on key issues. This survey was electronically conducted for our membership. Our response rate was encouraging with over 216 surveys completed from an initial distribution to 413 contacts.

As a cytotechnologist organization, we agree that the PT regulations include some entries that could be retained.

- 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.
- 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.

As a result of our recent electronic survey, we hold the following positions on specific recommendations from the PT Workgroup/CLIAC.

Issue-New Technology	Response
Do you recommend "slide" be changed to "challenge" to allow for flexibility in future technology (images or virtual slide tests at some point)?	**60% Y** 40% N
Do you recommend a transition phase for new technology?	**88% Y** 12% N

Several found the word "Challenge" confusing, but it was favored by a small majority (60%). Comments included "*Is it a challenging case"?* and "*images ultimately come from a slide so slide is still ok"*.

Options for new technology should be at the laboratory's discretion and reflect the daily work practice in that particular laboratory. A transition phase was supported (88%).

Issue-Frequency of Testing	Response
Current testing is annual, do you support testing at 3-year intervals?	**83% Y** 17% N

The 3-Year interval was supported by the majority (83%). Comments; *Annual testing is too costly. There are other educational programs completed annually and reported to CAP which could be reported to CMS as well. If you received 100% on your last PT, then you should be granted the 3 year testing.*

There were also comments supporting a two year interval, stating that once every three years will allow too many people to be missed.

Issue-Test Composition	Response
Current testing has 10 slides/2 hour limit for initial test; do you support 20 challenges per event for initial test/retest with 4 hour time limit?	25% Y **75% N**
Do you support leaving the four current categories?	**83% Y** 17% N
Do you support including at least one challenge from each of the four categories?	**87% Y** 13% N

Increasing the number and time allotted for the test was opposed by the majority (75%). Too time consuming and stressful to add slides was most often cited as the concern. Additionally, twenty slides would not necessarily prove more regarding proficiency than the 10 slide test. There might be a problem getting enough good quality slides and quality is more important than quantity. Those who supported (25%) favored the decreasing weight of an incorrect response, but only if the testing interval was increased.

Majority (83%) supported retaining the existing 4 categories with at least one challenge from each category (87%), especially if the test is 20 slides to prevent “gaming”.

Several comments, however, supported two categories for Cytotechnologist; NILM and Refer to Path or three categories UNSAT, NILM, SIL. Either would reflect more accurately the current cytotechnologist practice of interpreting gynecologic specimens as unsatisfactory, negative/normal or “refer to pathologist”. The problem of ambiguity of the unsatisfactory slide/response was mentioned.

Issue-Scoring	Response
Do you support changing language to state 'individuals who score <90% must. (As opposed to 'who fail')?	**88% Y** 12% N
Do you support changing grading scheme to remove the current automatic failure (-5) for HSIL called NILM?	**59% Y** 41% N
Current testing awards 5 points (Cytotechnologist) if a correct response LSIL is called Unsat. Do you support making the point value for a correct response LSIL slide called UNSAT '0'?	**59% Y** 41% N
Do you support a unified scoring system (Pathologists and Cytotechnologist scored equally)? CLIAC Proposed Model 'X' 20 Slide-Unified Scoring was shown in the survey.	**51% Y** 49% N
Do you support a separate scoring system for Pathologists and Cytotechnologist to reflect the differences in work practice?	**55% Y** 45% N

Scoring was by far the most controversial issue in our survey.

The language change (“score” vs. “failure”) was supported by the majority (88%).

The question regarding removal of automatic failure drew a slightly favored response (59%) with most comments stating, while a significant diagnosis, it can be very dependent on slide quality. In practice, Cytotechnologists can call ASC/ASCH and refer to pathologist. It is too high a penalty for an issue with subjective review.

The change regarding LSIL/UNSAT scoring was slightly favored (59%). Most comments related to concerns of the ambiguity of the unsatisfactory slide and the question of slide quality. 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 judgment to determine which adequacy estimations are best suited for their practices and patients. Some laboratories use a hierarchical review. (Several commented that UNSAT **must** go to pathologist- an erroneous statement.) 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.

Responses regarding the unified versus separate scoring systems were most confusing. Several stated they did not understand the model (Model X). The results show a unified scoring system slightly favored (**51%)** and a separate scoring system (**55%)** also favored. These responses present a puzzling and somewhat contradictory picture. Following are some of the comments as they were received.

The Pathologist has the final responsibility to sign out the case. They also have the ability to have the slide dotted thus they should have a different point system

I think since the Pathologist is making the final decision on these cases that they need to be graded more strictly. Otherwise if we are graded equally maybe the Cytotechs should be signing out the cases instead of a Pathologist.

They get to use the Cytotechnologists' dots on the slides and our answer sheets correct? Under this circumstance I support separate scoring. In real practice they use our marks and our interpretations to make their decisions.

I am unsure about this part of the PT. It doesn't seem fair to score them the same. If it is scored the same for paths and cytotechs hopefully we (Cytotechs) can use this in the future to help fashion a more PA type of position for cytotechnologists.

Pathologists need to be held to a higher standard. They have more education and are compensated for this. Otherwise pay Cytotechnologists the same as Pathologists.

The reality is, in practice, Cytotechs and Pathologists serve different roles. We should be 'graded' differently. The emphasis on Cytotech grading should be on locating abnormality, but since the Pathologists get dotted slides, this is not an aspect of their proficiency nor can they be tested on this - their 'grading' should be weighted toward definitive diagnosis.

When they pay cytotechnologists and Pathologists equally then they should have a unified scoring system. Until then, the Pathologists should be held to a stricter standard.

There are clear distinctions throughout the regulations for Technical and general supervisors and cytotechnologists. There should be some distinctions to reflect this work practice, compensation and medico-legal difference between CT and MD.

Issue - Validation	**Response**
Do you support required field validation of each challenge that is continuously updated throughout testing (in addition to 3 Pathologists consensus)?	**97%** Y 3% N
Do you support requiring biopsy confirmation of HSIL slides, but not requiring biopsy confirmation of LSIL slides?	46% Y **54%** N
Do you support requiring validation procedures to be disclosed by the vendor?	**98% Y**
Do you think the PT Provider must disclose appeals process in writing?	**96%**

Field validation was strongly supported (97%). Comments expressed the importance of including cytotechnologists in the validation 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. Having MDs validate on pre-dotted slides is an insufficient validation process and does not reflect practice.

Most (54%) requested confirmation on both LSIL and HSIL. However, some mentioned there would be a shortage of LSIL biopsies under new clinical practice guidelines.

Issue-Test Sites	Response
Do you support on-site testing for initial test?	**94% Y**
Do you think PT providers should allow options for test sites for missed test or retest?	**95% Y**

The test site options were supported by a large majority (94% and 95%). Testing at the participant laboratory offers the comfort of normal work environment and saves time and money. There was concern that jobs may be threatened as employers may not be willing to bear the costs of retests at off-site locales.

In summary, Proficiency Testing is but one component of an effective Quality Management System in Cytopathology. As quality assurance and quality improvement programs have demonstrated, screening is one small part of the overall successes that contribute to patient care and safety. Other proven effective, integrated and ongoing monitors are; Retrospective and 10% Rescreen, Cytology-Histology Correlation, and workload setting based on performance for Cytotechnologists every 6 months. We request a fair and meaningful PT program in balance with the other mandated quality management tools in cytology

The changes discussed in this document address the most immediate technical and scientific concerns with the current implementation of proficiency testing. The ASCT looks forward to the NPRM and further opportunity for participation in this important process.