Cytopathology and More | Pap proficiency testing—for whom, when, and why

Barbara A. Crothers, DO
Barbara Blond, MBA, MT(ASCP)
Beth Chmara, SCT(ASCP)

August 2014—It has been almost 10 years since gynecologic cytology proficiency testing, or Pap PT, was implemented in the United States. The CAP is one of three organizations with a Pap proficiency testing program. Pap PT is unique in medicine. In no other situation are licensed physicians or certified technologists required to pass a federally mandated, annual proficiency test before they can practice a skill for which they were trained. Individuals who do not pass Pap PT after two tests cannot practice the interpretation of gynecologic cytopathology until they pass the test. Physicians and other health professionals are usually awarded a license or certificate to practice based on their completion of an accredited training program, a comprehensive certification or licensing examination, and granting of privileges in a practice environment. Initial and subsequent board certification exams are part of the sum of their knowledge, not a test of their individual proficiency in a narrow, specific area.

Has Pap PT prevented unqualified cytologists from practicing gynecologic cytopathology? Approximately 10,000 to 12,900 people have taken Pap PT annually since 2005, the first year the test was introduced.1 From 2006 to 2013, of participants in the CAP Pap PT program, six physicians (0.016 percent) (no cytotechnologists)2 failed two or three retests. Over time, the first-time individual failure rate for the test has plateaued at about three percent annually,[1] and most of those who fail initially will pass on the second attempt. In fact, more than 99 percent of participants will pass in three or fewer attempts.[3] This suggests that most individuals who practice gynecologic cytopathology are proficient and that gains made by removing practitioners through Pap PT are slight.

Has Pap PT further reduced the rate of cervical cancer? In 2006, the age-adjusted incidence of invasive cervical cancer was 6.93 per 100,000, and in 2011, the last year for which complete SEER data exist, it was 6.73 per 100,000.4 The incidence of cervical cancer has declined steadily across all age groups since 1975, when it was 14.79 in 100,000,[4] largely owing to cervical cancer screening. Although there continues to be a slight overall decline in the incidence since 2006, this may be attributable to advances in Pap test technology, the introduction of HPV tests, and the development of new screening algorithms rather than proficiency testing.

The Centers for Medicare and Medicaid Services authorized three organizations to administer Pap PT: the CAP, the ASCP, and the state of Maryland Cytology PT Program. Enrollment in any of these programs is acceptable to comply with the federal regulation that all those who interpret Pap tests take and pass an annual Pap proficiency test. All of these programs follow the guidelines the CMS established under the Clinical Laboratory Improvement Amendments.[5]

There is still confusion about who needs to undergo Pap PT, how often, and under what circumstances. All individuals who screen or interpret Pap tests for patient care purposes must pass Pap PT at some point during the calendar year in which they practice. That is, a person can practice gynecologic cytology for an entire year and take the Pap PT anytime during that year, as long as he or she passes. If a person stops practicing gynecologic

cytology during a year, he or she still needs to pass Pap PT for that year to account for the period during which he or she reviewed Pap tests, regardless of the interval.

There may be exceptions to this general rule. If an individual dies or retires before the Pap PT, the laboratory cannot always be expected to have anticipated such, and the requirement is likely to be waived for that person. Pathologists who are within their first year of postgraduate practice are also exempt, as are those in fellowship or residency training. Cytotechnologists are not required to take the examination during the same calendar year in which they passed the ASCP Board of Certification test. If a cytologist (pathologist or cytotechnologist) is new to a laboratory that has already undergone its Pap PT for the calendar year, but that person has not yet taken and passed Pap PT that year, then the hiring laboratory is responsible for ensuring that the new employee takes the test during that calendar year. Pathologists and cytotechnologists who perform locum tenens work may be required to enroll in PT individually, at personal expense.
Laboratories should be aware of the CLIA restrictions on PT referral as they apply to Pap PT. Laboratories may inadvertently fall into noncompliance because of their usual laboratory practices and not understand that, under CLIA, their actions would be viewed as PT referral. For example, if a cytotechnologist screens and marks Pap PT examination slides and tests as the "primary screener" at a lab under a different CLIA certificate from the lab where the Pap examination slides are sent for pathologist interpretation, this is viewed as PT referral. To be in compliance, the cytotechnologists must prescreen and mark the Pap PT slides for the pathologists at the same laboratory in order to fall under one CLIA certificate.

Cytotechnologists may choose to take the test at their institutions using their own microscopes, or at the pathologist's laboratory, but they should submit only one test result form. When prescreening for a pathologist at a different CLIA-licensed laboratory, a cytotechnologist who already tested should use a courtesy screening form received from the test provider. The courtesy form is not returned to the test provider for grading. Similarly, a pathologist may travel to the cytotechnologist's laboratory for the examination. A "traveling" test taker should include both laboratory CLIA numbers for test report purposes. These logistics can be difficult for laboratories that share their workload between institutions or that centralize screening and processing.

Those who are unsuccessful in Pap PT must retake and pass the examination within the same year that they practice. Those who failed the test during one calendar year and wish to take the test the next calendar year must first take and pass the Pap PT they failed initially, and then take a second Pap PT for the current calendar year. Individuals unable to pass a second PT must have their casework for that year (up to the point of failure) reviewed for errors. There is no specific requirement for retraining before the second test, but a second failure mandates documented retraining and rescreening of slides previously screened or interpreted by that person.

The Gynecologic Cytopathology Quality Consensus Conference, convened in 2011, reviewed Pap PT as a quality measure and issued consensus statements on the practice.3 It was found that most laboratories do not implement remediation for initial failed tests. There is no solid, peer-reviewed evidence that Pap PT improves patient care, but PT test results over the years suggest that testing has discouraged primary screening pathologists, the subgroup of test takers who perform most poorly on PT, from practice.[2] The initial failure rate for primary pathologists (those who screen Pap tests without the benefit of prescreening by a cytotechnologist) is about 10 percent and represents about 30 pathologists from approximately 300 of that category tested annually. The higher failure rate among primary screening pathologists emphasizes the value to Pap test interpretation of a team approach that involves cytotechnologists.

1. Centers for Medicare and Medicaid Services. National cytology proficiency test results—initial test—2005 to 2012. Accessed June 14, 2014. Available at: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CytologyProficiency Testing.html.
2. Scores. College of American Pathologists database. Information accessed

June 18, 2014.
3. Howell LP, Nayar R, Savaloja L, et al. The role of proficiency testing in ensuring quality: findings from the College of American Pathologists Gynecologic Cytopathology Quality Consensus Conference working group 3. *Arch Pathol Lab Med*. 2013;137:183–189.
4. SEER Cancer Statistics Review, 1975–2011, National Cancer Institute. Bethesda, Md. http://seer.cancer.gov/csr/1975_2011/, based on November 2013 SEER data submission, posted to the SEER website, April 2014. Available at: http://seer.cancer.gov/csr/1975_2009_pops09/browse_csr.php?section=5&page=sect_05_table.05.html.
5. Clinical Laboratory Improvement Amendments of 1988. 42 CFR 493.855. Standard; Cytology: gynecologic examination. Accessed at www.gpo.gov on July 21, 2014.

[hr]

Dr. Crothers, chair of the CAP Cytopathology Committee, is cytopathology medical director at Walter Reed National Military Medical Center. Barbara Blond is CAP senior technical analyst, biostatistics. Beth Chmara is a technical manager, CAP Surveys. For more information, visit www.cap.org for a list of Pap PT frequently asked questions (in the website's Accreditation and Laboratory Improvement section, under About Pap PT).