

Comments on Gynecologic Cytology Proficiency Testing

Clinical Laboratory Improvement Advisory
Committee Meeting

February 8, 2006

George Birdsong, M.D.

American Society of Cytopathology

Emory University School of Medicine
Grady Memorial Hospital
Atlanta, GA

GYN Cytology PT

- While there have been many reports of individuals successfully taking the PT exam, there have also been many expressions of concern due to cases with ambiguous morphology and/or variable staining quality
- Instances of rare abnormal cells in slides with a reference interpretation of normal have been reported as a cause of missed questions

GYN Cytology PT

- Difference in failure rates between primary and secondary pathologist screening is noteworthy, however accuracy of the absolute percentage reported is open to question due to lack of initial field validation.
- Primary screening pathologists:
 - 3.6% of all examinees
 - 7.4% of pathologists

Gynecologic Cytology: Precision

Renshaw et al. 2003 - CAP Interlaboratory comparison program

Determined rates of exact match with reference interpretation for slides examined between 5 and 24 times

- Three expert cytopathologists at CAP had agreed that the cases were good examples and SILs were confirmed histologically
- 25745 responses on validated slides; 14353 on non validated slides

Gynecologic Cytology: Precision

- 29.7% of field validated and 28.6% of non-validated HSIL slides had a 100% exact match rate
- 18.3% of non-validated HSIL slides had <50% exact match rate
- HSIL was one the least reproducible/most difficult interpretations
 - Cytologic screening is associated with a 70% decrease in the rate of cervical cancer

Renshaw AA, Davey DD, Birdsong GG et al. Precision in gynecologic cytologic interpretation: a study from the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology. *Arch Pathol Lab Med.* 2003;127:1413-20.

Gynecologic Cytology: PT

- Coleman, et al., 1997 – UK
Reviewed results of bi-annual PT (7 cycles)
247 cytologists took the exam at least once
- Of 63 cytologists taking the exam 7 times, 7 failed one round despite scoring highly on the remaining rounds (6 had perfect scores in at least 5 rounds)
- 3 poor performers were identified

Gifford C, Green J, Coleman DV. Evaluation of proficiency testing as a method of assessing competence to screen cervical smears. *Cytopathology*. 1997;8:96-102.

GYN Cytology PT

- Field validation of slides used in initial PT was performed as PT results became available during 2005¹.

1. Gill, GW It's about MIME The ASC Bulletin. September 2005

Proficiency testing: Gynecologic cytology

- Field validation
 - Field validation is a process of establishing with statistical rigor that a specific case is a good example of its reference interpretation which can be consistently interpreted by trained professionals

Measuring the Significance of Field Validation in the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology

How Good Are the Experts?

- >10,000 cases selected as good examples of various cytodiagnostic entities for circulation after review by and consensus of three expert cytopathologists
- 15 to 19% of cases failed field validation
- Validation criteria stated in article

Proficiency testing: Gynecologic cytology

- Use of unvalidated slides
 - Decreases the certainty with which individuals needing remediation can be identified
 - Increases the risk of falsely labeling competent individuals as needing remediation
 - Poor performers will be more accurately identified if the slides are field validated.
 - The risk of spurious results is higher with slides which lack field validation

Proficiency testing : Gynecologic cytology

- New technologies: Not provided for in current schema which does not evaluate overall lab functioning
 - Computer assisted identification of fields which may contain abnormalities

Parker EM, Foti JA, Wilbur DC. FocalPoint slide classification algorithms show robust performance in classification of high-grade lesions on SurePath liquid-based cervical cytology slides. *Diagn Cytopathol*. 2004;30:107-10.

Biscotti CV, Dawson AE, Dziura B, Galup L, Darragh T, Rahemtulla A, Wills-Frank L. Assisted primary screening with the ThinPrep imaging system. *Am J Clin Path*. 2005;123:2

GYN Cytology PT

Despite lack of official sanctions from CMS, defacto sanctions exist

- Cost of repeat testing
- Loss of time
- Potential damage to professional reputation including threat of job loss
- > \$10,000,000 in direct and indirect costs associated with current implementation of PT; 99 individuals failed X4 or dropped out of testing out of 12786 (0.78%) initial examinees
- Institutional education budgets adversely affected

GYN Cytology PT

- The ASC is not opposed to the periodic evaluation of the quality of gynecologic cytology
- The ASC Mission Statement includes advocacy on behalf of patients
- However its current implementation which focuses exclusively on individuals and does not evaluate the functioning of the overall process in the laboratory is suboptimal, and its economic efficiency is questionable at best