Gynecologic Cytology-Histology Correlation Guideline

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Correlation of cytology with corresponding histologic specimens is one of the most informative and beneficial quality assurance practices. Abnormal Pap tests can be correlated with follow-up biopsies, which allows positive predictive value (PV+) to be calculated.[1] Negative Pap tests preceding histologically proven squamous intraepithelial lesions (SILs) of the cervix present potential educational opportunities for both the cytotechnologist and cytopathologist when there are screening or interpretive errors, and for the entire patient care team when there are sampling errors. Negative Pap tests that precede histologically proven SILs cannot be used to compute negative predictive values or sensitivity because biopsies are not routinely taken following negative Pap tests.[2]

Time intervals between the cytologic and histologic specimens should be specified, and ideally limited to approximately six months to avoid non-correlation due to regression of lesions; however exact time interval limits should be determined by individual laboratories with consideration given to the percentage of follow-up biopsies submitted within various time intervals and the level of abnormality of the corresponding Pap tests.[1,3] Episodes of care that encompass multiple visits may produce multiple Pap tests and biopsies, so careful consideration should also be given to which of these to include in statistical calculations. Pap tests taken at colposcopy may or may not represent the performance of Pap tests taken for screening, and Pap tests taken more than 6 months prior to colposcopy may show a weaker correlation with histology than Pap tests taken within six months. The optimal time frame for correlating a biopsy with a Pap test diagnosed as SIL is 60 days. For quality assurance purposes, 100 days and up to 365 days may be more appropriate.[3]

Pertinent components of a cytologic-histologic correlation protocol include the following:

1. Inclusion Criteria:
   a. Criteria for inclusion of cases, including the minimum/maximum time intervals between cytology specimens and histology specimens.
2. Protocol for when correlations are performed and by whom:
   a. At the time of histology sign-out (real-time)
   b. Periodic, retrospective correlation at defined intervals (i.e. monthly, quarterly, bi-annually).
      i. Real-time correlations facilitate comprehensive evaluations of the material available for a case, leading to a more useful report for the clinician and patient. However, they are an additional step which may slow down the sign out process.
      ii. Retrospective correlations may be more convenient for laboratory personnel since it allows a more narrow focus on the task. It is greatly facilitated by a laboratory information system (LIS) module expressly designed for the purpose.
3. Search Logistics:
   a. Grid or algorithm for assessing the correlation of the two specimens:
      i. Depending on the capabilities of the LIS, the initial portion of the process may be partially automated. For example, many if not most LISs are capable of generating a list of cytology-histology pairs in which the cytologic specimen precedes the histologic specimen within a defined time frame. In addition, many if not most modern LIS utilize "canned" comments for cytology reporting, and this data is stored

in a database (as opposed to a text document). If the histologic diagnosis is also coded (for example, with SNOMED codes) and stored in a database, the LIS may able to perform the task of juxtaposing the cytology and histology specimens and making a preliminary determination of whether or not the specimens correlate.

ii. Optionally, the data may be subdivided by results of ancillary molecular studies such as human papillomavirus (HPV) testing and p16 immunohistochemical staining. This information may be informative for quality assurance purposes, but it is not a required part of the process. If including HPV testing, one should specify the assay that is used.

4. Correlation Definitions:
   a. Definitions for correlating and non-correlating specimens with gradations in between if deemed appropriate.
   b. For example, a discrepancy could be classified as a major (2 step difference between Pap and biopsy result) or minor (1 step difference between Pap and biopsy result.) While some variation across laboratories in assessment of the correlation of cytology and corresponding histology specimens is inevitable, particularly regarding abnormalities less than HSIL, most laboratories would agree that a high-grade SIL (HSIL) in one modality paired with a negative result in the other modality constitutes a major discrepancy. More variation across laboratories in assessment of, for example, an ASC-US Pap and a corresponding biopsy read as negative or LSIL is to be expected, and there are no universally agreed upon standards for this process.[1]

Episodes of care that encompass multiple visits may produce multiple Pap tests and biopsies, so careful consideration should also be given to which of these to include in statistical calculations.

5. Tabulation of Data/Calculated parameters:
   a. A system for tabulating the data (i.e. spreadsheet, database program, specific LIS module, etc.) should be defined.
   b. Parameters to be calculated (i.e. percentages of pairs with exact agreement, minor disagreement, major disagreement, etc.)
   c. PV+

   The output of this process can optionally be further enhanced by the creation of histograms depicting the number of cytology-histology pairs with exact agreement, minor overcalls and undercalls, and major overcalls and undercalls. This could be further sub-divided for each cytologic or histologic diagnosis, but pairs in which at least one of the specimens is HSIL or greater are most important clinically. Individual laboratories should determine the most appropriate system for themselves.
6. A defined procedure for investigation/evaluation of non-correlating specimen pairs
   a. Definition of false positive (FP)
   b. Definition of false negative (FN)
   c. Pick list of common explanations for FP and FN major discrepancies (i.e. sampling, screening, difference of opinion, HPV (+), overcall, under call, etc.)[4]
7. Statistical Calculations:
   a. Establish criteria for expected PV+ within the laboratory. While there are no universally agreed upon benchmarks for PV+, several studies which provide this parameter have been published or have presented data from which it may be calculated.[5-8] PV+ rates vary from approximately 60% to >95% in these studies. The rates are not directly comparable between studies because the details of the correlation protocols may vary. The Royal College of Pathologists of Australia has set a standard of ≥65% for the PV+ of HSIL.[9] Other parameters such as the percentage of pairs with exact agreement or agreement within one grade will also be of interest from the standpoint of education and quality improvement, but are not likely to be statistically meaningful because of verification bias (lack of histology follow-up on patients with negative cytology.) More complex methods of compensating for verification bias exist but are more applicable in research settings than for routine clinical practice[2]

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