Variability in Cytologic-Histologic Correlation Practices and Implications on Patient Safety

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Abstract

Context: The Clinical Laboratory Improvement Amendments of 1988 require that laboratories perform cytologic-histologic correlation, although the optimal methods and the value of performing correlation have not been determined.
Objectives. To determine the similarities and differences in how laboratories perform cytologic-histologic correlation.
Design. One hundred sixty-two American laboratories were sent a letter requesting copies of the materials they used in the cytologic-histologic correlation process. The returned materials were classified into the categories of forms, logs, and tally sheets. A checklist (derived from the College of American Pathologists Laboratory Accreditation Cytopathology Checklist) was developed to classify the *minimum* (15) and *additional* data points that laboratories collected when they performed a correlation.
Participants. American pathology laboratories.
Main outcome measures. Percentage of laboratories that recorded *minimum* and *additional* data points. Frequency that specific *minimum* data points were recorded.
Results. The response frequency was 32.1% and a total of 84 cytologic-histologic correlation materials were obtained. The only *minimum* variables recorded on forms or logs by more than 50% of laboratories were cytology case number, sign-out cytology diagnosis, surgical pathology case number, and sign-out surgical pathology diagnosis. Nine (17.3%) laboratories did not record data on forms, logs, or tally sheets. The mean number of *minimum* and *additional* variables recorded on forms was 6.5 and 8.7, respectively.
Conclusions. Laboratories record data from the cytologic-histologic correlation process in a number of ways, indicating the lack of standardization of the data collection process.

Introduction

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) mandated the performance of cytologic-histologic correlation as an effort to improve anatomic pathology quality. In the cytologic-histologic correlation process, if a cytology specimen and a surgical pathology specimen are obtained from the same anatomic site (within a given timeframe), the diagnoses are compared in order to detect possible discrepant cases.
Correlation is a method of secondary viewing, a form of redundancy, which may be used as an error detection and prevention tool.
Although correlation is a useful method for error detection, the lack of uniformity in performing correlation is problematic for several reasons. The absence of uniformity (e.g., the specific cytologic and histologic diagnoses that are considered discrepant) leads to difficulties in laboratories comparing data. Second, the lack of standardization allows for laboratories to perform correlation with variable rigor (e.g., some laboratories simply record the discrepant diagnoses and other laboratories review the cases prior to sign out). Third, the lack of correlation guidelines does not allow for laboratories to employ "best practices" in order to use correlation data for self-improvement. In this study, American laboratories are surveyed on how they currently perform correlation in order to devise the optimal tools to be used for the correlation process.

Materials and Methods

In September 2002, AHRQ funded four institutions (University of Pittsburgh, Henry Ford Hospital, University of Iowa, and Western Pennsylvania Hospital) to design patient safety initiatives for anatomic pathology practice. These initiatives are based on error data that are collected through current error detection methods, such as cytologic-histologic correlation. One of the first steps in the AHRQ project was the creation of an error database that stores cytologic-histologic correlation errors. In order to standardize the cytologic-histologic correlation practices at the four institutions, we first wanted to measure current American cytologic-histologic correlation practices in order to determine differences in methods and the effects of these differences on data collection.

In 2002, we sent a letter to 162 American laboratories requesting participation in a process that measured current cytologic-histologic correlation practices. The letters were sent to the directors of cytopathology fellowship programs and pathology residency programs and to a sample of the members of the Association of Directors of Anatomic and Surgical Pathology. We requested that the laboratory fax or send de-identified copies of their current cytologic-histologic correlation material.

We classified the received material into the categories of forms, logs, or tally sheets. We defined forms as containing individual patient (i.e., case) data, often presented in a questionnaire format. Logs were defined as containing data from multiple patients, often presented in a tabular format. Tally sheets contained counts of variables over a given time span. Some laboratories sent a combination of forms, logs, and tally sheets, and many laboratories only sent one type of data collection material. Some laboratories further specified if the data collection material was for gynecologic or non-gynecologic specimens.

We constructed a list of variables in order to compare the amount and specific cytologic-histologic correlation information recorded by each institution. The list of variables was derived from the CAP's Commission for Laboratory Accreditation Cytopathology Checklist and from the materials sent by the individual laboratories.

Based on the CAP's Cytopathology Checklist, we considered that 15 items could be considered key variables when performing cytologic-histologic correlation. These variables were derived from individual Cytopathology Checklist questions that focused on case discrepancy and correlation. We classified these variables as the *minimum* set of variables that could be collected.

The 15 specific *minimum* items are:
1. Cytology case number
2. Sign-out cytology diagnosis
3. Sign-out cytologist
4. Original cytotechnologist diagnosis (for gynecologic cases)
5. Sign-out cytotechnologist (for gynecologic cases)
6. Review cytology diagnosis
7. Review cytologist
8. Surgical pathology case number
9. Sign-out surgical pathology diagnosis
10. Sign-out surgical pathologist
11. Review surgical pathology diagnosis
12. Review surgical pathologist
13. Significance of discrepancy (i.e., effect on patient care or presumed impact on patient care)
14. Action taken (i.e., what occurred as a result of identification of the discrepancy)
15. Reason for correlation (i.e., if correlation was part of normal cytologic-histologic correlation, as a result of clinician concern, etc.)

Based on review of the cytologic-histologic correlation forms, logs, and tally sheets, we observed that some laboratories collected additional items that related to the cytologic-histologic correlation procedure. We classified these items as *additional* variables, which could be classified into seven categories:
1. Patient information: name, medical record number, history, date of birth, etc.
2. Cytology specimen information: specimen site, collection dates, clinician, and cytotechnologist comments about specimen and original diagnosis
3. Surgical specimen information: specimen site, collection date, clinician, and comments about specimen and original diagnosis
4. Review information: review date and comments about the review
5. Discrepancy information: reasons for the discrepancy, statement on if the diagnoses correlated, and other comments about concordance or discordance
6. Counts: number of specimen parts, number of slides, etc.
7. Other information: department and physician contact information and other information that did not fit into the above categories

We calculated the number of *minimum* and *additional* data points that each laboratory recorded in their cytologic-histologic correlation material. We used these data to compare the cytologic-histologic correlation processes conducted across laboratories.

Table 1. Classification of cytologic-histologic correlation material sent by individual laboratories.

Collection material	Number of laboratories (%)
Forms only	16 (30.1)
Logs only	15 (28.9)
Forms and logs only	4 (7.7)
Forms, logs, and tally sheets	2 (3.9)
Tally sheets only	1 (1.9)
Forms and tally sheets only	1 (1.9)
Logs and tally sheets only	4 (7.7)
No forms, logs, or tally sheets	9 (17.3)
Specification of forms/logs for gynecologic or non-gynecologic correlation	
Specification of gynecologic	12 (23.1)
Specification of non-gynecologic	3 (5.8)
No specification of gynecologic or non-gynecologic	36 (69.2)

Table 2. Number of laboratories with specific *minimum* variables of cytologic-histologic correlation material.

Variable	Number of laboratories with variable on forms (%)
Cytology case number	58 (82.9)
Sign-out cytology diagnosis	56 (71.4)
Sign-out cytologist	22 (31.4)
Original cytotechnologist diagnosis (for gynecologic cases)	4 (6.5)
Sign-out cytotechnologist (for gynecologic cases)	10 (16.1)
Review cytology diagnosis	24 (34.3)
Review cytologist	13 (18.6)
Surgical pathology case number	43 (61.4)
Sign-out surgical pathology diagnosis	42 (60.0)
Sign-out surgical pathologist	7 (10.0)
Review surgical pathology diagnosis	9 (12.9)
Review surgical pathologist	2 (2.9)
Significance of discrepancy	8 (11.4)
Action taken	28 (40.0)
Reason for correlation	16 (22.9)

Table 3. Mean number and range of variables collected on cytologic-histologic institutional collection forms.

	Number of the 15 minimum variables			Total number of variables (minimum/additional)			Number of additional variables		
Type of material	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
Forms/Logs	5.0	0	11	10.8	0	31	5.7	0	21
Forms	6.5	3	11	15.2	8	31	8.7	2	21
Logs	5.0	1	8	9.4	2	18	4.4	0	12
Gynecologic specified	5.3	1	9	12.3	2	23	6.9	1	16
Non-gynecologic specified	6.9	5	11	11.6	5	22	4.8	0	13
Not Specified	5.7	2	11	12.5	3	31	6.9	0	21

Table 4. Mean number and range of *additional* variables collected on cytologic-histologic institutional collection forms.

	Mean number of additional variables (range)						
Type of material	Patient	Cytology specimen	Surgical specimen	Review	Discrepan cy	Counts	Other	Total
Forms/Logs	0.9 (0-3)	0.9 (0-3)	0.6 (0-5)	2.6 (0-10)	1.1 (0-3)	0.3 (0-9)	0.5 (0-4)	6.9 (0-21)
Forms	1.4 (0-3)	1.2 (0-9)	0.8 (0-5)	3.7 (0-10)	1.2 (0-3)	0.1 (0-2)	0.6 (0-4)	9.0 (0-21)
Logs	0.4 (0-2)	0.6 (0-2)	0.3 (0-2)	1.6 (0-6)	0.9 (0-2)	0.5 (0-9)	0.3 (0-3)	4.7 (0-12)
Gyn specified	1.3 (0-3)	0.4 (0-1)	0.3 (0-2)	2.8 (0-7)	0.9 (0-2)	0.6 (0-4)	0.6 (0-4)	6.9 (1-16)
Non-gyn specified	0.1 (0-1)	0.9 (0-2)	0	3.5 (1-8)	0.5 (0-1)	1.3 (0-4)	1.3 (0-4)	6.8 (2-15)
Not specified	0.9 (0-3)	1.1 (0-3)	0.8 (0-5)	2.4 (0-10)	1.2 (0-3)	0.3 (0-4)	0.3 (0-4)	6.9 (0-21)

Figure 1: *Minimum expected* and *additional* variables listed on forms only. Bold line represents *minimum expected* variables that should be present (n=15).

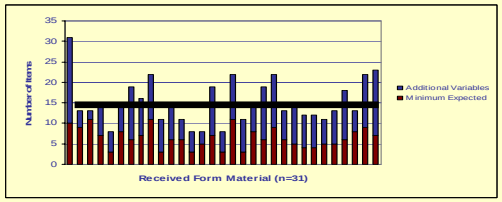
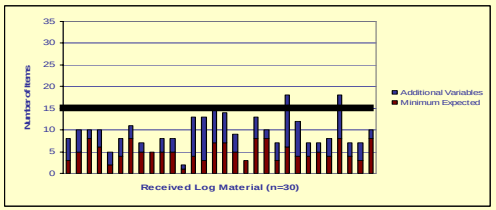


Figure 2. *Minimum expected* and *additional* variables listed on logs only. Bold line represents *minimum expected* variables that should be present (n=15).



Results

The response frequency was 32.1% (52 laboratories responded), and a total of 84 cytologic-histologic materials were obtained. Nineteen of the respondents sent multiple types of material. The number of laboratories that sent forms, logs, tally sheets, and combinations of these data collection material is shown in **Table 1**. The majority of laboratories either used forms or logs, although some laboratories did not use any data collection material. Forty-three laboratories sent forms and or logs that were analyzed in this study (26.5% of all laboratories). The number of laboratories that further specified if the data collection material was for gynecologic or non-gynecologic specimens also is shown in **Table 1**.

Table 2 shows the number and percentage of laboratories that listed the 15 individual *minimum* variables on their cytologic-histologic correlation forms or logs. The only *minimum* variables listed by more than 50% of laboratories were cytology case number, sign-out cytology diagnosis, surgical pathology case number, and sign-out surgical pathology diagnosis. Information regarding cytotechnologist, sign-out surgical pathologist, and assessment of the significance of the discrepancy generally was not recorded.

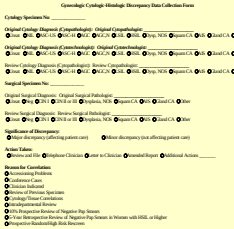
Table 3 shows the mean, maximum, and minimum number of *minimum*, *additional* and total (*minimum* and *additional*) variables listed on the correlation material. The type of correlation material is classified into the categories of forms and logs (if the laboratory sent both), forms only, and logs only (if the laboratory sent only forms or logs). The number of variables also is listed by laboratory that subclassified their forms or logs as for gynecologic or for non-gynecologic specimens. No laboratory listed all 15 of the *minimum* variables, and the majority of laboratories recorded data on less than 50% of the *minimum* variables. The majority of laboratories reported collecting *additional* data points, and the total number of items collected (*minimum* and *additional*) varied considerably by laboratory. In general, laboratories listed more *additional* variables than *minimum* variables on their correlation collection material.

Table 4 shows the mean number and range of *additional* variables collected on cytologic-histologic institutional data collection forms. The columns show the categories of the *additional* variables. Although the mean number tended to be low, the range was high and some institutions collected up to 10 *additional* variables on the cytologic-histologic correlation forms. The most frequently collected *additional* variable was on the review process itself, such as the date or additional comments amount the review.

Figure 1 shows the number of *minimum expected* and number of *additional* variables listed on the forms received (individual forms are presented on the X-axis). For example, the first form recorded 10 *minimum expected* and 21 *additional* variables with a total of 31 variables. None of the forms contained all 15 *minimum expected* variables.

Figure 2 shows the number of *minimum expected* and number of *additional* variables listed on logs received (individual logs are presented on the X-axis). For example, the first log recorded 3 *minimum expected* and 5 *additional* variables with a total of 8 variables. Compared to the number of variables collected on forms (**Figure 1**), fewer variables were collected on logs. None of the logs contained all 15 *minimum expected* variables.

Figure 3: Suggested gynecologic cytologic-histologic correlation Form that incorporates *minimum expected* variables.


Gynecologic Cytologic-Histologic Discrepancy Data Collection Form

Cytology Specimen No. _____

Original Cytology Diagnosis (Cytopathologist): Original Cytopathologist: _____
○ Unsat ○ Neg ○ ASC-US ○ ASC-H ○ LSIL ○ HSIL ○ SCC ○ AGC ○ Dysp, NOS ○ Squam CA ○ Glan CA ○ Metast CA ○ Other

Original Cytology Diagnosis (Cytotechnologist): Original Cytotechnologist: _____
○ Unsat ○ Neg ○ ASC-US ○ ASC-H ○ LSIL ○ HSIL ○ Dysp, NOS ○ Squam CA ○ Glan CA ○ Metast CA ○ Other

Review Cytology Diagnosis (Cytopathologist): Review Cytopathologist: _____
○ Unsat ○ Neg ○ ASC-US ○ ASC-H ○ LSIL ○ HSIL ○ Dysp, NOS ○ Squam CA ○ Glan CA ○ Metast CA ○ Other

Surgical Specimen No. _____

Original Surgical Diagnosis: Original Surgical Pathologist: _____
○ Unsat ○ Neg ○ CIN 1 ○ CIN II or III ○ Dysplasia, NOS ○ Squam CA ○ Glan CA ○ Metast CA ○ Other

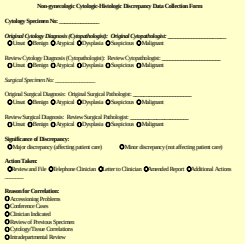
Review Surgical Diagnosis: Review Surgical Pathologist: _____
○ Unsat ○ Neg ○ CIN 1 ○ CIN II or III ○ Dysplasia, NOS ○ Squam CA ○ Glan CA ○ Metast CA ○ Other

Significance of Discrepancy:
○ Major discrepancy (affecting patient care) ○ Minor discrepancy (not affecting patient care)

Action Taken:
○ Review and File ○ Telephone Clinician ○ Letter to Clinician ○ Forwarded Report ○ Additional Actions _____

Reason for Correlation:
○ Accessioning Problems
○ Conference Cases
○ Clinician Indicated
○ Review of Previous Specimen
○ Cytology/Tissue Correlations
○ Interdepartmental Review
○ 10% Prospective Review of Negative Pap Smears
○ 5 Year Retrospective Review of Negative Pap Smears in Women with HSIL or Higher
○ Prospective-Randomized High Risk Rescreen

Figure 4. Suggested non-gynecologic cytologic-histologic correlation Form that incorporates *minimum expected* variables.


Non-gynecologic Cytologic-Histologic Discrepancy Data Collection Form

Cytology Specimen No: _____

Original Cytology Diagnosis (Cytopathologist): Original Cytopathologist: _____
○ Unsat ○ Benign ○ Atypical ○ Dysplasia ○ Suspicious ○ Malignant

Review Cytology Diagnosis (Cytopathologist): Review Cytopathologist: _____
○ Unsat ○ Benign ○ Atypical ○ Dysplasia ○ Suspicious ○ Malignant

Surgical Specimen No: _____

Original Surgical Diagnosis: Original Surgical Pathologist: _____
○ Unsat ○ Benign ○ Atypical ○ Dysplasia ○ Suspicious ○ Malignant

Review Surgical Diagnosis: Review Surgical Pathologist: _____
○ Unsat ○ Benign ○ Atypical ○ Dysplasia ○ Suspicious ○ Malignant

Significance of Discrepancy:
○ Major discrepancy (affecting patient care) ○ Minor discrepancy (not affecting patient care)

Action Taken:
○ Review and File ○ Telephone Clinician ○ Letter to Clinician ○ Forwarded Report ○ Additional Actions _____

Reason for Correlation:
○ Accessioning Problems
○ Conference Cases
○ Clinician Indicated
○ Review of Previous Specimen
○ Cytology/Tissue Correlations
○ Interdepartmental Review

Discussion

Our findings show that laboratories record cytologic-histologic correlation data in a number of ways, implying that the cytologic-histologic correlation process is not standardized. No two laboratories collected the same variables for cytologic-histologic correlation, and laboratories generally do not record basic data points that would seem to be necessary for accurate recording of data from the correlation process. It further follows that although CLIA '88 requires the performance of cytologic-histologic correlation, the benefit of this performance may vary considerably from laboratory to laboratory.

The CAP recognizes the importance of performing cytologic-histologic correlation and consequently, created the Laboratory Accreditation Cytopathology Checklist. We abstracted 15 *minimum* variables that could be recorded if laboratories performed cytologic-histologic correlation using this Checklist as a guide for data collection. Based on the returned forms and/or logs, no laboratory recorded all 15 *minimum* variables, and the mean number of *minimum* variables collected ranged from 5 to 7, depending on the data collection tool.

It is possible that laboratories perform cytologic-histologic correlation by examining their material for these 15 *minimum* variables and simply do not record these data points on forms or logs. However, if laboratories look for these data points when performing cytologic-histologic correlation, it would be of greater utility if these data points were recorded. Utility of the correlation process partly depends on examining discordant rates related to specific diagnoses, specimen types, or practitioners. Ideally, laboratories would reduce discordant rates by learning from previous errors and implementing patient safety measures based on case types with higher discordant frequencies or discordancies that have more marked impact on patient care.

We used these data to construct cytologic-histologic gynecologic and non-gynecologic correlation forms that have been used by the participating grant sites. Versions of these forms are shown in **Figure 3** and **4**.