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The Role of Monitoring Interpretive Rates, Concordance Between Cytotechnologist and Pathologist Interpretations Before Sign-Out, and Turnaround Time in Gynecologic Cytology Quality Assurance Findings From the College of American Pathologists Gynecologic Cytopathology Quality Consensus Conference Working Group 1

Karen M. Clary

Diane D. Davey

Sonya Naryshkin

R. Marshall Austin

Nicole Thomas

See next page for additional authors

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Findings From the College of American Pathologists Gynecologic Cytopathology Quality Consensus Conference Working Group 1

Karen M. Clary, MD; Diane D. Davey, MD; Sonya Naryshkin, MD; R. Marshall Austin, MD, PhD; Nicole Thomas, CT(ASCP); Beth Anne Chmara, CT(ASCP); Chiara Sugrue, MBA, MS, SCT(ASCP); Joseph Tworek, MD

● ***Context.***—**The College of American Pathologists (CAP) conducted a national survey of gynecologic cytology quality assurance (QA) practices. Experts in gynecologic cytology were asked to join 5 working groups that studied the survey data on different aspects of QA. Evaluating the survey data and follow-up questions online, together with a review of pertinent literature, the working groups developed a series of preliminary statements on good laboratory practices in cytology QA. These were presented at a consensus conference and electronic voting occurred.**

Objective.—**To evaluate a set of QA monitors in gynecologic cytology. Working group 1 evaluated (1) monitoring interpretive rate categories for Papanicolaou tests (Pap tests), (2) concordance of cytotechnologist and pathologist interpretations before sign-out, and (3) turnaround time for Pap tests.**

Data Sources.—**The statements are based on a survey of gynecologic cytology QA practice patterns and of opinions from working group members and consensus conference attendees.**

Conclusions.—**The outcomes of this process demonstrate the current state of practice patterns in gynecologic cytology QA. Monitoring interpretive rates for all Bethesda System categories is potentially useful, and it is most useful to monitor interpretive rates for cytotechnologists individually and in comparison to the entire laboratory. Laboratories need to determine what level of discrepancy between cytotechnologist and pathologist interpretations of Pap tests is important to track. Laboratories should consider formalizing procedures and policies to adjudicate such discrepant interpretations. Turnaround time should be monitored in gynecologic cytology, but individual laboratories should determine how to measure and use turnaround time internally.**

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Monitoring interpretive rate categories for Papanicolaou tests (Pap tests), concordance of cytotechnologist and pathologist interpretations before sign-out, and turnaround time are 3 categories of monitors that may be useful for quality assurance in gynecologic cytology. These quality assurance measures were evaluated as part of a larger project by the College of American Pathologists (CAP) that surveyed a wide range of quality assurance monitors in gynecologic cytology. The monitoring of interpretive rates is mandated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and by accrediting agencies, including the CAP. Most frequently, such rates are monitored for the entire laboratory and for cytotechnologists, and less frequently for pathologists. Determining what rates should be monitored, who should be monitored, how frequently, and how such monitoring should

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From the Department of Pathology, Rochester General Hospital, Rochester, New York (Dr Clary); the Department of Clinical Sciences, University of Central Florida, and Orlando Veterans Administration Medical Center, Orlando, Florida (Dr Davey); the Department of Pathology, Mercy Health System, Janesville, Wisconsin (Dr Naryshkin); the Department of Pathology, Magee-Womens Hospital, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania (Dr Austin); CAP Pap Program (Ms Thomas) and the Department of Cytologic Surveys (Ms Chmara), College of American Pathologists, Northfield, Illinois; the Division of Cytopathology, Hofstra Northshore Long Island Jewish School of Medicine, New Hyde Park, New York (Ms Sugrue); and the Department of Pathology, St Joseph Mercy Hospital, Ann Arbor, Michigan (Dr Tworek).

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Reprints: Karen M. Clary, MD, Department of Pathology, Rochester General Hospital, 1425 Portland Ave, Rochester, NY 14621 (e-mail: karen.clary@rochestergeneral.org).

occur within the laboratory were issues addressed in this study.

Cytotechnologists and pathologists work in tandem to identify potentially precancerous and cancerous cells on Pap tests. Disagreements may arise between the cytotechnologist and pathologist as to the presence of abnormal cells, or the degree of abnormality identified on the Pap test. The manner in which these disagreements are handled will potentially impact patient care. Tracking such disagreements between cytotechnologists and pathologists may be used as a quality metric. Objectives for quality assurance guidelines are to determine if and how concordance/discordance of cytotechnologist and pathologist interpretations should be used as a metric. Other questions are how and when to adjudicate discrepancies between cytotechnologists and pathologists, and what types of cases should be shown to a third party before sign-out of the Pap test by the pathologist.

Turnaround time (TAT) for Pap tests is a readily quantified measure in the cytology laboratory. However, the effectiveness of TAT as a quality metric is debatable. Turnaround time may relate more to customer satisfaction or to laboratory staffing than to laboratory quality. Monitoring TAT may have a negative impact if its use causes undue pressure on cytotechnologists, resulting in rushing Pap test screening. If and how monitoring TAT should be part of a quality assurance plan in the cytology laboratory is at issue.

METHODS

The CAP, with support from the Centers for Disease Control and Prevention (CDC), conducted a national survey of quality assurance practices in gynecologic cytology. This Web-based survey was developed by the 3 senior authors of the CAP project with input from national organizations (CAP Cytopathology Resource Committee, the American Society of Cytopathology, the American Society for Cytotechnology, and the American Society of Clinical Pathology), and CDC colleagues. The survey was distributed to all laboratories that participate in gynecologic cytology proficiency testing in the United States, and more than 540 survey responses were received. For details of the complete process of this study, including the development of the survey, enhanced Web-based input, and culmination in a consensus conference, see the introductory article.[1] In short, expert cytopathologists and cytotechnologists were recruited to become part of 5 working groups that studied the survey data on different aspects of quality assurance. These working groups added follow-up questions to the survey, which were available online and elicited additional opinions. Evaluating the data and follow-up questions, together with a review of the literature, the working groups developed a series of preliminary statements on good laboratory practices in cytology quality assurance and presented these at a consensus conference in Rosemont, Illinois, on June 4, 2011. Participants in the conference included working group members, representatives from national cytopathology and cytotechnology organizations, Centers for Medicare and Medicaid Services (CMS), the CDC, and individuals who accepted invitations after completing the written survey. Representatives from the working groups presented their draft statements to the audience participants who voted electronically on the issues. Some statements received a clear consensus from the audience, some had clearly no consensus, and for others, consensus was questionable. The stratified consensus responses were categorized as "agreement": 70% to 79%; "moderately strong agreement": 80% to 89%; "strong agreement": 90% to 98%; and "nearly complete agreement": 99% to 100%. The voting resulted in a number of consensus good laboratory practice statements. Limitations of the process include the small number of participants in the consensus conference, and the basis largely on expert opinion, rather than on evidenced-based practices.

RESULTS

Monitoring Interpretive Rates

The monitoring of interpretive rates is common practice among the laboratories surveyed, although which rates are monitored and the frequency of monitoring varies (Tables 1 and 2). Some interpretive rates are either mandated by CLIA regulations and/or required as a component of laboratory certification by deemed organizations, especially the CAP. Theoretically, some interpretive rates, such as the percentage of cancer, are population-specific indices that are not expected to vary over time unless there is a shift in the demographics of the patient population served. And, as different laboratories serve populations of women with different demographics, interpretative rates would be expected to vary among laboratories. For example, CAP benchmarking data from 2006 showed that the rate of low-grade squamous intraepithelial lesion (LSIL) on liquid-based Pap tests varied among laboratories from a low of 1.1% at the fifth percentile to more than 7% at the 95th percentile. Rates for high-grade squamous intraepithelial lesion (HSIL) varied more than 20-fold from 0.1% to 2%.[2]

That being said, cervicovaginal cytology does have a subjective component to interpretations, and thus interpretive rates could vary as a reflection of thresholds for specific interpretations, such as between atypical squamous cells of undetermined significance (ASCUS) and LSIL, for example. In this regard, the monitoring of interpretive rates might be useful for intralaboratory monitoring of consistency, which cytotechnologists and pathologists use in applying interpretative criteria. Published scientific data concerning the usefulness of the application of the monitoring of specific diagnostic rates to an effective quality assurance program, however, is quite scant, and thus this area is wide open for future research exploration. That which might seem logical or intuitive on the surface may not always bear out after subjection to scientific scrutiny. For example, the limited published data concerning the correlation of overall abnormal pickup rates and false-negative fraction[3] showed no correlation. Findings such as this are important to consider when making choices as to which metrics to use and for which purposes.

Survey Results.—Another example would be that of regular monitoring of categories of abnormalities subject to poor interobserver and intraobserver variability, such as ASCUS. Such monitoring makes sense in regard to an individual laboratory's reproducibility of results, and the subsequent trust that clinicians may put in such reports. Indeed, the monitoring of ASCUS was reported by 83.9% of 528 laboratories (Table 1), the highest rate for any of the diagnostic categories, indicating a great degree of consensus that ASCUS is an important diagnostic rate to monitor.

ASCUS is also one of the categories that is most subject to "diagnostic drift" and variability among both pathologists and cytotechnologists. Because the ASCUS to squamous intraepithelial lesion ratio (ASCUS:SIL ratio) has much less variability than the ASCUS rate, this monitor is more useful for interlaboratory comparisons, such as in benchmarking.[4] Indeed, in our written survey, the ASCUS:SIL ratio was the only interpretive rate opined to be very useful by more than half of respondents (53.5 %) (Table 3). A study correlating cytotechnologists' ASCUS:SIL ratios with sensitivity[5] showed that the mean screening sensitivity for cytotechnologists with ASCUS:SIL ratios less than 1.5 was

Table 1. Actively Monitored Diagnostic Rates (N = 528)						
	Laboratory		Cytotechnologist		Pathologist	
Diagnostic Rate	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
None	9	1.7	17	3.2	56	10.6
NILM	407	77.1	374	70.8	169	32.0
Unsat	443	83.9	380	72.0	182	34.5
LSIL	437	82.8	398	75.4	208	39.4
HSIL	435	82.4	399	75.6	207	39.2
SCC	383	72.5	337	63.8	180	34.1
Other malignancies	355	67.2	311	58.9	161	30.5
ASCUS	443	83.9	404	76.5	215	40.7
ASC-H	398	75.4	359	68.0	194	36.7
AGC	399	75.6	361	68.4	192	36.4
ASCUS:SIL ratio	424	80.3	324	61.4	198	37.5
NILM:SIL ratio	96	18.2	82	15.5	46	8.7
Other	90	17.0	75	14.2	46	8.7

Abbreviations: AGC, atypical glandular cells; ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; ASCUS:SIL ratio, the ratio of cases with an interpretation of atypical squamous cells of undetermined significance to cases with squamous intraepithelial lesions; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial lesion or malignancy; NILM:SIL ratio, the ratio of cases with an interpretation of negative for intraepithelial lesion or malignancy to cases with squamous intraepithelial lesions; SCC, squamous cell carcinoma; Unsat, unsatisfactory.

significantly less than that for cytotechnologists whose ASCUS:SIL ratio was more than 3.0. The authors also suggested that an ASCUS:SIL ratio less than 1.5 for a cytotechnologist might be useful as a surrogate marker for inadequate screening sensitivity. Note that this study compared ASCUS:SIL ratios of individual cytotechnologists before final interpretation of cases by pathologists, and thus higher ratios are expected. Indeed, the 2006 CAP benchmarking data[2] showed that the average laboratory ASCUS:SIL ratio was about 1.5. However, too much emphasis on a low ASCUS:SIL ratio in a laboratory could potentially have a negative impact on laboratory sensitivity. A recent clinical trial showed that several laboratories with ASCUS:SIL ratios of 1.5 or less had less than 50% adjusted screening sensitivity for cervical intraepithelial neoplasia grade 2+.[6] Therefore, benchmarking data without data correlating it to quality outcomes can be deceptively reassuring.

Interestingly, 41.9% of written survey respondents reported that other undesignated diagnostic rates, not listed on the survey, were useful to them in monitoring quality (Table 3). This obviously requires more study.

The most common interval for monitoring of diagnostic rates was monthly (Table 2). As diagnostic rates for entities other than ASCUS tend to be rather stable over time unless there is a shift in demographics, the monthly frequency of monitoring probably reflects a logistic convenience, as many laboratories collect the raw data for calculating error rates on a monthly basis. For rates with expected fluctuations, such as ASCUS or ASCUS:SIL, monthly monitoring might make more sense. However, such frequent monitoring may pose a problem for small laboratories with extremely small volumes, such as 500 or less cases per year, as their rates may fluctuate widely just by statistical chance. Also, comparing their rates to published benchmarks may also be misleading for the same reason. Some laboratories use a rolling 12 months of data collection, which can be analyzed monthly, quarterly, or at some other interval, based upon the suitability to individual laboratories. This is an area that needs more research.

Table 2. Monitoring Frequency		
How Frequently Are the Diagnostic Rates Monitored?		
	Frequency	Percentage
Daily	9	1.8
Weekly	3	0.6
Monthly	333	64.8
Bimonthly	4	0.8
Quarterly	62	12.1
Semiannually	65	12.6
Annually	32	6.2
Other	6	1.2

Follow-up Questions Posted on Internet Site.—The detailed comments from the follow-up online questions were interesting. Only 56% of 87 respondents reported ever seeing a shift in an actively monitored diagnostic rate laboratory-wide. A similar percentage reported ever seeing a shift in an actively monitored individual diagnostic rate, but the reasons attributed to the changes were different. The most common factors (mentioned in 25% of the comments each) attributed to the shift were a change in technique/methodology, such as adding imaging or switching to a different liquid-based method and personnel receiving feedback about recently missed cases, review of diagnostic criteria, and others. For shifts in individual diagnostic rates, the common factor attributed was the individual receiving feedback or participating in open discussion, supporting the intuitive importance of providing feedback to individuals. Common but less frequently cited reasons were a change in personnel (pathologists or cytotechnologists) and implementation of human papillomavirus (HPV) testing or review of HPV results.

When asked why participants found that monitoring ASCUS was helpful, most alluded to the fact that ASCUS is the clinical decision point, and an indicator of the threshold of abnormality. Participants felt that monitoring ASCUS rates prevents overcalling and undercalling and helps to keep interpretations within the laboratory uniform. However, the follow-up online questions revealed that of 87 respondents, 71% and 68% reported that ASCUS rates varied greatly both among cytotechnologists and pathologists, respectively. This seems to challenge the impression that merely monitoring the ASCUS rates would necessarily

Table 3. Usefulness of Diagnostic Rates in Monitoring Quality							
Diagnostic Rate	N	Average Rank	Very Useful 5, %	4, %	3, %	2, %	Not Useful 1, %
NILM	439	3.6	33.3	21.6	24.1	11.8	9.1
Unsat	492	4.0	44.3	23.8	20.3	7.1	4.5
LSIL	490	4.0	41.8	26.9	22.9	5.7	2.7
HSIL	490	4.1	46.5	24.1	22.2	4.5	2.7
SCC	432	3.7	36.6	21.8	23.4	10.9	7.4
Other malignancy	409	3.6	35.7	20.3	24.9	10.3	8.8
ASCUS	492	4.2	51.0	23.8	18.1	5.3	1.8
ASC-H	459	4.0	44.2	24.4	21.4	6.5	3.5
AGC	451	3.8	33.3	28.8	23.9	8.9	5.1
ASCUS:SIL ratio	465	4.2	53.5	23.0	16.1	5.2	2.2
NILM-SIL ratio	132	3.5	33.3	18.9	23.5	11.4	12.9
Other	86	3.5	41.9	11.6	17.4	12.8	16.3

Abbreviations: AGC, atypical glandular cells; ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; ASCUS:SIL ratio, the ratio of cases with an interpretation of atypical squamous cells of undetermined significance to cases with squamous intraepithelial lesions; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial lesion or malignancy; NILM:SIL ratio, the ratio of cases with an interpretation of negative for intraepithelial lesion or malignancy to cases with squamous intraepithelial lesions; SCC, squamous cell carcinoma; Unsat, unsatisfactory. Rankings based on a scale of 1 to 5: not useful to very useful.

produce uniformity. One respondent mentioned that cytotechnologists who miss ASCUS also tend to miss HSIL, an observation that is supported by the literature.[3]

When asked which interpretive rates were felt to not be useful, most comments included relatively rare but significant interpretations such as atypical glandular cells, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion (ASC-H), and cancer. This issue was discussed in detail at the conference, and the suggestion was made to combine these categories into a monitor that could be followed even in low-volume laboratories. However, 43.5% of attendees at the consensus conference felt that this was not useful. Only future research will clarify this newly identified controversy.

Another category felt to be problematic, and one documented now to lead to many unnecessary procedures, was normal endometrial cells in women older than 40 years. This was also a topic of discussion at the conference. Scientific data show that the only women with normal-appearing endometrial cells who may require endometrial sampling or ultrasound assessment are those who are postmenopausal or having clinically abnormal bleeding.[7]

From the follow-up online questions, most reporting laboratories (95%) monitor the total abnormal rate. Eighty-two percent monitor both laboratory and individual rates. More than half of the respondents (58%) felt that cytotechnologists and pathologists should have access to their diagnostic rates. Such feedback was felt to be helpful because it provided "peer pressure" to outliers, making counseling easier when needed; helped people know how they were doing in relation to others in the laboratory and to CAP benchmarks; improved education and sharing of cases; helped to refine skills and cytologic criteria; and helped with accuracy and managing of diagnostic thresholds.

Fifty-nine percent of online respondents felt that each person's individual interpretive rates should be shared confidentially with him or her. Several commented that it was helpful to openly publish/display interpretive rates within the laboratory, but that people should not be individually identifiable. A few commented that the sharing of interpretive rates could actually be a negative, depending upon how they were used, for example, as a basis for merit raises. While there are correlations between some rates and performance, such as the correlation between ASCUS:SIL ratios and sensitivity cited above, such correlations are not absolute; therefore, it is important to use more than 1 metric. This once again brings up the importance of tying benchmarks to clinically significant metrics such as error rates or sensitivities for significant lesions.

Consensus Good Laboratory Practice Statements and Comments.—Table 4 lists the good laboratory practice statements generated from the survey, the Internet follow-up questions, and opinions of the authors for monitoring interpretive rates in gynecologic cytology. These statements were voted on at the consensus conference, and in cases where there was no clear initial consensus, the statements were revised and voted on again.

Concordance of Cytotechnologist and Pathologist Interpretations

Tracking discrepancies between cytotechnologists and pathologists is incorporated into the evaluation of individual performance as mandated by CLIA. However, the methods for monitoring and analyzing discrepancies are not specified. The CAP checklist requires documentation of each individual's diagnostic discrepancies and corrective actions taken (CYP.07660). The CAP checklist also requires comparison of individual cytotechnologist interpretation to the final diagnosis in gynecologic specimens signed out as abnormal, as part of the 6-month workload assessment (CYP 0.08575). Most laboratories incorporate some evaluation of discrepancy analysis as part of the every-6-month workload review, and this has been advocated as a possible quality metric.[8–10] Establishing a baseline level of discrepancies is important so that trends can be analyzed. Individual discrepancy rates can be compared to the laboratory rate, and individual rates can be tracked over time. Laboratories also need to determine what level of discrepancy is important to track and whether upgraded or downgraded interpretations, or both, need to be monitored. Laboratories should also consider formalizing procedures and policies to adjudicate discrepant interpretations of Pap tests between cytotechnologists and pathologists before sign-out of the Pap test. Adjudication of discrepancies may be challenging in laboratories with 1 pathologist and cytotechnologist or in laboratories with only a pathologist.

Survey Results.—From the survey, greater than 73% of laboratories actively monitor the rates at which a pathologist upgrades a cytotechnologist's diagnosis at the time of initial

Table 4. Consensus Good Laboratory Practice Statements: Monitoring Interpretive Rates

1. Monitoring of interpretive rates for all Bethesda System categories is potentially useful, as each Bethesda System category is clinically relevant.
   Do you agree with the consensus statement?
   Yes: 94.3%
   No: 5.7%
   Should standard categories of interpretive rates be monitored in all laboratories?
   Yes: 85.1%
   No: 6.3%
   Should each individual laboratory choose which interpretive rates to monitor?
   Yes: 20.7%
   No: 79.3%
2. It is most useful to monitor interpretive rates for cytotechnologists individually and in comparison for the entire laboratory.
   Do you agree with the consensus statement?
   Yes: 100%
3. It is currently unclear whether or not monitoring interpretive rates for individual pathologists beyond laboratory rates as a whole is useful.
   Is monitoring interpretive rates of individual pathologists useful to you?
   Yes: 85.7%
   No: 12.9%
   Other: 1.4%
   Is this an area that should be explored?
   Yes: 90.5%
   No: 3.2%
   Other: 6.4%
4. Consider monitoring combined interpretive rates of "dangerous abnormals," defined as cancer, suggestive of cancer, HSIL, AGC, and ASC-H.
   Do you think that using the combined category "dangerous abnormals" could be useful?
   Yes, in low-volume/low-prevalence laboratories only: 15.9%
   Yes, in any laboratory: 34.8%
   No: 43.5%
   Don't know: 5.8%
5. Monthly monitoring of interpretive rates may be useful, if possible.
   Is monthly monitoring:
   Too frequent: 43.1%
   Not frequent enough: 1.7%
   Just right: 55.2%

5a. *Revised statement*: Regular monitoring of interpretive rates may be useful and the individual laboratory should determine the frequency of monitoring.
   Do you agree?
   Yes: 98.2%
   No: 1.9%

6. Providing feedback of interpretive rates is important.
   Should individual interpretive statistics be provided to cytotechnologists and pathologists as feedback?
   Yes, regularly: 88%
   No, not at all: 1%
   Only as part of scheduled employee reviews: 11%

Abbreviations: ACG, atypical glandular cells; ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; HSIL, high-grade squamous intraepithelial lesion.

Table 5. Monitoring Change in Diagnosis

	Frequency	Percentage
The rates at which a pathologist upgrades a cytotechnologist's diagnosis at the time of initial sign-out are actively monitored per cytotechnologist:		
Yes	376	73.3
No	137	26.7
The rates at which a pathologist downgrades a cytotechnologist's diagnosis at the time of initial sign-out are actively monitored per cytotechnologist:		
Yes	312	62.5
No	187	37.5

sign-out, and greater than 62% of laboratories actively monitor the rates at which a pathologist downgrades a cytotechnologist's diagnosis at the time of initial sign-out (Table 5). The most critical upgrades monitored are from negative for intraepithelial lesion or malignancy (NILM) to either LSIL or to HSIL or greater, monitored respectively by 97.9% and 96.6% of the 381 laboratories that responded to this survey question (Table 6). Upgrades from NILM to ASCUS and to ASC-H are also frequently monitored by 74.8% and 81.9% of laboratories, respectively, as are upgrades from ASCUS to HSIL, monitored by 83.2% of laboratories. Monitoring upgrades from LSIL to HSIL and ASC-H to HSIL was not as frequent, with only 65.9% and 57.0% of laboratories, respectively, following these rates.

The most frequent and most important downgrades monitored by laboratories are from HSIL to NILM and LSIL to NILM, each monitored by more than 94% of the 320 laboratories that responded to this question in the survey (Table 7). Monitoring of downgrades from either ASC-H or ASCUS to NILM is followed respectively by 80.6% and 72.5% of laboratories, and monitoring downgrades of HSIL to either LSIL or to ASC-H is followed respectively by 64.4% and 60.6% of laboratories.

In adjudicating discrepancies between cytotechnologists' and pathologists' diagnoses, only 49.5% of laboratories have a written policy specifying the process to resolve 2-grade discrepancies, and only 25.2% have such a written policy in cases of 1-grade discrepancies (Table 8). For 2-grade discrepancies, the Pap test in question is frequently shown by the pathologist to a second person before sign-out: 32.2% to the original cytotechnologist, 24.7% to another pathologist, and 4.5% to another cytotechnologist. In only 33.7% of laboratories that responded did the pathologist diagnosis stand without further action. By contrast, in the case of 1-grade discrepancies, such as from LSIL to ASCUS, most laboratories (68.5%) responded that the pathologist's diagnosis stands and only 27.6% responded that the case was shown to a second person.

Follow-up Questions Posted on Internet Site.—Seven additional questions were posted on a Web site in an attempt to supplement the written survey questions. The number of responses, ranging from 62 to 87, was low when compared to the number of responders to the written survey. From the responses, most pathologists (60%) seek additional review of particular cases before downgrading a cytotechnologist diagnosis (Table 9). The most frequent cases that elicit second review are HSIL (78%), atypical glandular cells (54%), and ASC-H (41%). Similarly, 37 of 61 cytotechnologists indicated that they seek additional review before forwarding a case to a pathologist (Table 10). The most frequent case shown by a cytotechnologist is a Pap test interpreted as atypical glandular cells.

Forty-nine percent of pathologists indicated that they did not routinely confirm an abnormal Pap test result by showing it to another individual before sign-out (Table

Table 6. Upgrade Rates Monitored for Cytotechnologists (N = 381)								
	Pathologist Diagnosis							
	ASCUS		ASC-H		LSIL		HSIL or Greater	
Cytotechnologist Diagnosis	Frequency	Percentage	Freq	Percentage	Freq	Percentage	Freq	Percentage
NILM	285	74.8	312	81.9	373	97.9	368	96.6
ASCUS	...	...	179	47.0	216	56.7	317	83.2
LSIL	...	...	169	44.4	...	...	251	65.9
ASC-H	...	...	...	...	...	...	217	57.0

Abbreviations: ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; Freq, frequency; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial lesion or malignancy.

11). Of those pathologists that did confirm a diagnosis, this was most frequently done at the discretion of the pathologist and not for any specific interpretive category. Frequently, Pap tests not interpreted as abnormal or reactive are routinely reviewed by pathologists before sign-out (Table 12). The most frequent Pap test in this category is one containing herpes, shown by 81% of responders. Unsatisfactory Pap tests and those with benign endometrial cells follow those with herpes at 59% and 44%, respectively. Written responses were solicited in the "other" category, chosen by 29%. Many of these comments indicated that endometrial cells identified in women either older than 40 years or older than 50 years, or the presence of *Actinomyces*, were Pap tests that were frequently shown: (45% and 35%, respectively).

Consensus Good Laboratory Practice Statements and Comments.—Table 13 lists the good laboratory practices generated by data from the written survey, the Internet discussion site, and opinion of the authors for monitoring concordance of cytotechnologist and pathologist interpretations. These were voted on at the consensus conference and in cases where there was no clear consensus, the statements were reworded and resubmitted for voting.

As shown in Table 13, statement 1a, while there was strong support to actively monitor upgrades of cytotechnologist interpretations, particularly of NILM to SIL+, by pathologists, there was not clear consensus on which other cytotechnologist interpretations should also be monitored. The statement was revised and resubmitted.

Cytotechnologists are responsible for screening slides for potential abnormalities. The rate at which interpretations are upgraded was deemed to be an important quality monitor by 79.7% of conference participants (Table 13, statement 1b). However, there was no consensus as to the definition of a significant discrepancy. Some laboratories may choose to monitor any case upgraded from negative to abnormal (ASCUS+) plus upgrades from ASCUS or LSIL to HSIL. Other laboratories may prefer to define upgraded discrepancies more narrowly with normal to SIL+ counted. At the very least, upgrades of NILM to SIL+ should be considered as a monitor.

As shown in Table 13, statement 2, there was less consensus as to whether downgraded interpretations should be monitored. Some laboratories only monitored significant downgrades, while other laboratories had broader definitions. Pathologists are responsible for making the final determination on abnormal cases, based not only on cellular features but also clinical history and management implications. There is an expectation that many specimens interpreted as potentially atypical by cytotechnologists will be downgraded to negative by pathologists, and similarly, there will be some cases in which a minor downgrade is made because there is uncertainty as to the nature of an abnormality. An example is a case downgraded from HSIL to ASC-H when there is uncertainty, in order to prevent potential overtreatment. In the written survey sent to laboratories, many participants agreed that only significant downgrades should be monitored. For example, 96.3% of laboratories monitor downgrades of HSIL to negative, whereas only 60.6% monitor downgrades from HSIL to ASC-H.

Laboratories may address significant discrepancies in interpretations between cytotechnologists and pathologists in a variety of ways. Often the pathologist uses individual discretion in determining which types of cases should be adjudicated by a third person. In the written survey relating to 2-step discrepancies, 33.7% of respondents stated that the pathologist's diagnosis stands without further action, while most either reviewed the case with the cytotechnologist (32.2%) or consulted a second pathologist (24.7%). At the conference, 62.5% strongly agreed that discrepancies of 2 degrees or more should be showed to a third person when possible, and 29.2% agreed with reservations. Since clear consensus was not obtained on which diagnostic categories may benefit from review by a third person (Table 13, statement 3a), the question was restated and resubmitted

Table 7. Downgrade Rates Monitored for Cytotechnologists (N = 320)								
	Pathologist Diagnosis							
	NILM		ASCUS		ASC-H		LSIL	
Cytotechnologist Diagnosis	Freq	Percentage	Freq	Percentage	Freq	Percentage	Freq	Percentage
ASCUS	232	72.5	...	...	...	...	...	...
ASC-H	258	80.6	158	49.4	...	...	...	...
LSIL	302	94.4	189	59.1	...	...	...	...
HSIL or greater	308	96.3	274	85.6	194	60.6	206	64.4

Abbreviations: ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; Freq, frequency; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial lesion or malignancy.

Table 8. Additional Monitoring Characteristics		
	Frequency	Percentage
In cases of a 2-grade or greater discrepant diagnosis between a pathologist and a cytotechnologist, how is the discrepancy most commonly resolved?		
The pathologist's diagnosis stands without further action	172	33.7
By reviewing the Papanicolaou test with original cytotechnologist	164	32.2
Discrepancies are shown to a second pathologist	126	24.7
Other	24	4.7
Discrepancies are shown to a second cytotechnologist	23	4.5
By HPV testing	1	0.2
There is a written laboratory policy specifying the process for resolution of a 2-grade discrepancy:		
Yes	252	49.5
No	257	50.5
In cases of a 1-grade or greater discrepant diagnosis between a pathologist and a cytotechnologist, how is the discrepancy most commonly resolved?		
The pathologist's diagnosis stands without further action	350	68.5
By reviewing the Papanicolaou test with original cytotechnologist	94	18.4
Discrepancies are shown to a second pathologist	37	7.2
Other	18	3.5
Discrepancies are shown to a second cytotechnologist	10	2.0
By HPV testing	2	0.4
There is a written laboratory policy specifying the process for resolution of a 1-grade discrepancy:		
Yes	129	25.2
No	383	74.8

Abbreviation: HPV, human papillomavirus.

for a vote (statement 3b). Examples of cases meeting these criteria would be upgrades from NILM to HSIL or downgrades of cases from HSIL+ to negative. Small laboratories with only a single cytotechnologist and pathologist have challenges in adjudicating discrepancies. Some mechanisms for addressing discrepancies in small laboratories include reviewing the case at a multiheaded microscope, correlating the interpretation with later biopsies, and sending select cases out of the laboratory for outside consultation. Obtaining HPV testing in certain situations may be a possibility, but this has to be tempered by the fact that there is a small false-negative rate of HPV testing in HSIL and cancer cases.[11,12] Furthermore, HPV testing should be requested in consultation with the clinician after discussion of possible pitfalls. Regardless of how individual laboratories may handle discrepancies, 73.7% of consensus conference participants agreed that laboratories should have policies about which categories of discrepancies should be reviewed by a third individual before sign-out. These policies will clarify expectations for both cytotechnologists and pathologists and provide more uniform handling of specimens, which may impact significantly on patient care. Policies dealing with 1-grade discrepancies, such as from HSIL to ASC-H, are not as critical as policies handling a 2-grade discrepancy such as from HSIL to NILM. In the former case, there is no or minimal change in patient management, while in the latter, patient management will be different.

Certain types of high-risk specimens may especially benefit from review by a third person; examples are atypical glandular cells and those results, such as HSIL, that will impact on the patient's receiving colposcopy and biopsy. Glandular lesions are problematic and are not infrequently the cause of litigation. The voting at the consensus conference reflects the awareness of difficulties in detecting glandular lesions. Only 27.7% thought it unnecessary to show a premalignant or malignant glandular lesion to a third person, whereas 39.4% thought this was not needed

Table 9. For Pathologists, Are There Particular Cases for Which You Seek Additional Review Before Downgrading a Cytotechnologist Diagnosis?		
	Frequency	Percentage
Yes	37	60
No	18	29
Unsure	7	11
Total	**62**	**100**
If Yes, for Which of the Following Diagnoses? (Check All That Apply)		
ASCUS	10	27
ASC-H	15	41
LSIL	7	19
HSIL	29	78
AGC	20	54

Abbreviations: AGC, atypical glandular cells of undetermined significance; ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion.

Table 10. For Cytotechnologists, Are There Particular Cases for Which You Seek Additional Review Before Forwarding a Case on to a Pathologist?		
	Frequency	Percentage
Yes	37	61
No	22	36
Unsure	2	3
Total	**61**	**100**
If Yes, for Which of the Following Cases? (Check All That Apply)		
ASCUS	16	46
ASC-H	15	43
LSIL	2	6
HSIL	9	26
AGC	20	57

Abbreviations: AGC, atypical glandular cells of undetermined significance; ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion.

Table 11. Are Abnormal Interpretations Confirmed by Showing the Papanicolaou Test Slide to Another Individual Before Final Sign-Out?

	Frequency	Percentage
Yes	33	49
No	33	49
Unsure	1	1
Total	**67**	**100**
If Yes, for Which of the Following Diagnoses? (Check All That Apply)		
ASCUS	9	22
ASC-H	11	28
LSIL	4	10
HSIL	12	30
AGC	12	30
Individual cases at the discretion of the pathologist only	25	62

Abbreviations: AGC, atypical glandular cells of undetermined significance; ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion.

for similarly severe squamous lesions (Table 13, statements 4 and 5).

Laboratories should have policies as to which cases benefit from review by a second person (cytotechnologist or pathologist), even if not required by CLIA. These may include unsatisfactory, endometrial cells in women older than 40 years, glandular cells in women post hysterectomy, and herpes. CLIA requires that all reactive and potentially abnormal cases be reviewed and confirmed by a pathologist. However there is no requirement that certain Bethesda categories be confirmed by a second individual. Some of these types of specimens have important clinical management implications. Examples include unsatisfactory specimens, endometrial cells, and certain types of organisms including herpes simplex virus (Table 13, statement 6a). Greater than 90% of consensus conference participants agreed that laboratories should have policies as to which cases benefit from such review (Table 13, statement 6b). Specimens designated as "unsatisfactory" generally require early repeat according to American Society for Colposcopy and Cervical Pathology management guidelines.[13] Additional review helps to promote intralaboratory reproducibility in application of adequacy criteria. Furthermore, patients who have received chemotherapy or radiation therapy may have lower-cellularity specimens, and there are no data to suggest a minimum numeric threshold; thus, the pathologist may evaluate clinical history and exercise clinical judgment in certain cases designated by the cytotechnologist as unsatisfactory.[13] Endometrial sampling is recommended for postmenopausal women with benign-appearing endometrial cells, while women age 40 years or older who are still having menstrual cycles and are asymptomatic can return to routine screening.[14] In addition, differentiating atypical glandular cells from shed endometrial cells is challenging, and such cases benefit from additional review.

Table 12. For Which Papanicolaou Test Findings (Other Than Abnormal and Reactive) Do You Require Pathologist Review?

	Frequency	Percentage
Benign endometrial cells	31	44
Unsatisfactory	41	59
Obscuring factors	10	14
Herpes	57	81
Individual cases at the discretion of the pathologist only	16	23
Other glandular processes	25	36
Other	20	29

Turnaround Time

Turnaround time has been historically associated with causing pressure on cytotechnologists to increase productivity at the expense of quality.[15] With the implementation of CLIA '88, however, strict regulations have limited the number of slides cytotechnologists are allowed to screen per day and individual workload limits are assessed biannually. Given these quality measures, during the last decade the concept of TAT has evolved to become a readily quantifiable measure in the cytology laboratory and to have an impact on quality.[16] A timely reporting of results translates into timeliness of patient care. However, it may be argued that gynecologic cytology is a screening test, which decreases the sense of urgency for the results.

Turnaround time is generally defined as the time a specimen is accessioned in the laboratory to the time the report is signed out or finalized. However, there is variability among laboratories in defining when the TAT cycle starts and when it ends.

Turnaround time can be considered a reliable indicator for evaluation of laboratory staffing by identifying bottleneck areas in any part of the test cycle. Turnaround time is monitored to examine the functionality of the overall service, including slide preparation, cytotechnologist screening, and pathologist sign-out. Turnaround time also relates to customer satisfaction and may influence decisions about where to refer gynecologic cytology work, especially considering the competitive environment in the current health care arena.[17] In addition, as patients become more knowledgeable about laboratory testing through targeted marketing and other means, the demand for prompt reporting increases, thus influencing the necessity to monitor TAT.

Survey Results.—From the survey, a laboratory's expectations on Pap test TAT varied widely, from 1 to 7 or more days, with a median Pap test TAT of 3 business days (Table 14). Laboratories reported that actual TAT was less than the expected TAT, as shown in the percentile distributions in Table 14. How laboratories define and measure TAT varied; 57.2% of respondents defined the starting point as the date/time of accessioning the Pap test, while 24.1% used date/time of specimen receipt, and 14.6% used date/time of specimen collection. There was more universal agreement on the definition of the ending point for TAT measurement, as date/time report finalized (89.1%). Other definitions of ending points included date/time results delivered to physician (4.2%) and date/time case reviewed by technologist or pathologist (4.0%). The most common frequency of TAT monitoring was monthly (46.6%), followed by daily (20.4%) and quarterly (11.6%). The most common metric used to measure TAT variance was percentile distribution within a certain TAT (54.2%), followed by mean TAT (32.4%) and percent of cases deviating from TAT expectation (15.5%) (Table 15).

Table 13. Consensus Good Laboratory Practice Statements: Monitoring Concordance of Cytotechnologist and Pathologist Interpretations	
	Percentage
1a. Actively monitor rates at which a pathologist upgrades cytotechnologist interpretations before sign-out.	
A. Agree, NILM to SIL+ (negative to SIL or higher)	25.8
B. Agree, NILM to SIL+, also ASCUS to HSIL	25.8
C. Agree, A and B plus NILM to ASCUS	17.7
D. Agree, any upgrades to abnormal plus LSIL or ASC-H to HSIL	29.0
E. Do not monitor upgrades	1.6
1b. *Revised statement*: Actively monitor rates at which a pathologist *upgrades* cytotechnologist interpretations before sign-out. Definition of upgrades should be determined by the laboratory. Do you agree?	
A. Yes	79.7
B. No	15.3
C. Other	3.4
D. Other	1.7
2. Actively monitor rates at which a pathologist *downgrades* cytotechnologist interpretations before sign-out. Do you:	
A. Agree, HSIL+ or LSIL to NILM only	65.2
B. Agree, ASCUS+ (all abnormal) to NILM	10.1
C. Agree: all abnormal to NILM, and HSIL to ASC-H or LSIL	14.5
D. Do not monitor downgrades	10.1
3a. Show discrepancies of 2 degrees or more to a third person when possible. Do you:	
A. Strongly agree	62.5
B. Agree with reservations	29.2
C. Disagree	8.3
3b. *Revised statement*: Laboratories should have policies about which categories of discrepancies should be reviewed by a third individual before sign-out. Do you agree?	
A. Yes	73.7
B. No	22.8
C. Other	3.5
4. Some cases benefit from review by a third person even if not upgraded/downgraded (squamous). Which cases benefit from third-person review (squamous)?	
A. ASC-H and greater	19.7
B. HSIL and greater	18.3
C. Squamous cell carcinoma only	22.5
D. Not necessary	39.4
5. Some cases benefit from review by a third person even if not upgraded/downgraded (glandular). Which cases benefit from third-person review (glandular)?	
A. Both atypical glandular cells and adenocarcinoma	55.4
B. Adenocarcinoma only	15.4
C. Not necessary	27.7
D. Other	1.5
6a. Some cases benefit from routine review by a second person even if CLIA does not require confirmation by a pathologist. Which cases benefit from routine review by second person (cytotechnologist or pathologist) even if not required by CLIA?	
A. Herpes	4.0
B. Endometrial cells in women >40 y	0
C. Glandular cells in women post hysterectomy	2.7
D. B and C only (glandular processes)	16.2
E. All examples (A, B, C)	59.5
F. Not necessary routinely (only at the discretion of the screener)	17.6
6b. *Revised statement*: Laboratories should have policies as to which cases benefit from review by a second person (cytotechnologist or pathologist), even if not required by CLIA. These may include: –Unsatisfactory –Endometrial cells in women >40 y –Glandular cells in women post hysterectomy –Herpes Do you agree?	
A. Yes	90.7
B. No	9.3

Abbreviations: ASC-H, atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; CLIA, Clinical Laboratory Improvement Amendments of 1988; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial lesion or malignancy; SIL, squamous intraepithelial lesion.

Follow-up Questions Posted on Internet Site.—Five additional questions were posted on the Web site to attempt to supplement the written survey questions. The number of responses on the Web site (76) was much lower than the responses to the written survey. From the responses, 59% of laboratories agreed that monitoring TAT is an effective quality metric. Monitoring TAT was reported to be useful for monitoring staffing needs in the laboratory, and as a metric for customer service. Thirty-three percent of laboratories felt that monitoring TAT is not an effective quality metric, with several opinions stating that a faster TAT does not equate to quality work. Eight percent of respondents were "unsure" if

Table 14. Turnaround Time (TAT) Expectations

	Frequency	Percentage
Laboratory's expected Papanicolaou test TAT in business days		
1	33	7.7
2	90	21.0
3–4	122	28.4
5–6	123	28.7
>7	61	14.2
Laboratory's *median* Papanicolaou test TAT in business days		
1	60	15.2
2	109	27.5
3–4	163	41.2
5–6	40	10.1
>7	24	6.1

monitoring TAT is an effective quality metric. There was evidence of some misinformation for the requirement of TAT monitoring, with 61% of respondents believing that TAT monitoring was mandated, primarily by clinical guidelines. Thirty-two percent of respondents report that monitoring TAT negatively affects quality, including causing undue pressure on cytotechnologists to meet screening quotas. Of the 21% who report that monitoring TAT positively affects quality, timely patient care and use as a staffing monitor were given as examples. Forty-seven percent of respondents were "unsure" if TAT constraints negatively or positively affect quality, with many stating TAT did not affect quality, or that TAT could have both positive and negative effects.

Table 16 lists the good laboratory practice statements generated from the written survey, Internet questions and comments, and opinions of the authors, on monitoring Pap test TAT. These statements were voted on at the consensus conference. Most consensus conference participants agreed that TAT should be monitored in gynecologic cytology (Table 16, statement 1). Awareness of TAT should be a consideration in the overall laboratory quality performance, including addressing individual capabilities and limits. However, the use of TAT monitoring should never compromise the quality of the Pap test evaluation in any phase of the cycle. Laboratory directors and managers should be aware of the potential negative implications of monitoring TAT. Thirty-two percent of respondents report that monitoring TAT negatively affects quality, including causing undue pressure on cytotechnologists to meet screening quotas, possibly leading to increase in false-negative rates and screening errors, and possibly leading to increased ASCUS rates.

Table 15. Turnaround Time (TAT) Monitoring

	Frequency	Percentage
Which metric is used to measure TAT variance? (N = 491)[a]		
Percentile distribution within a certain TAT	266	54.2
Mean TAT	159	32.4
Percentage of cases deviating from TAT expectation/standard	76	15.5
Median TAT	61	12.4
Average length of deviation from TAT expectation/standard	39	7.9
Other	36	7.3
How frequently does the laboratory monitor Papanicolaou test TAT?		
Daily	104	20.4
Weekly	40	7.9
Monthly	237	46.6
Bimonthly	4	.8
Quarterly	59	11.6
Semiannually	13	2.6
Annually	23	4.5
Other	29	5.7
When does the clock start ticking for the TAT measurement?		
Date/time accessioned	297	57.2
Date/time received for processing	125	24.1
Date/time collected	76	14.6
Other	8	1.5
Date/time ordered by provider	7	1.3
Date/time received for screening	5	1.0
Date/time results submitted for reporting	1	.2

[a] Multiple responses were allowed.

Table 16. Consensus Good Laboratory Practice Statements: Turnaround Time (TAT) in Gynecologic Cytology

1. Turnaround time should be monitored in gynecologic cytology. Do you agree?
   A. Yes: 80.3%
   B. No: 19.7%
2. We should not attempt to establish a universally acceptable TAT in gynecologic cytology. Do you agree?
   A. Yes: 90.1%
   B. No: 9.9%
3. Individual laboratories should determine how to measure/define TAT. Do you agree?
   A. Yes: 74.3%
   B. No: 25.7%
4. Individual laboratories should determine the frequency of TAT monitoring. Do you agree?
   A. Yes: 98.6%
   B. No: 1.4%
5. Individual laboratories should determine the metric used to measure TAT variance. Do you agree?
   A. Yes: 91.3%
   B. No: 8.7%

There was strong agreement among consensus conference participants that we should not attempt to establish a universally acceptable TAT in gynecologic cytology (Table 16, statement 2). A specific TAT for Pap tests is not required as certification criteria for laboratory inspections[18] (CAP, American Society of Cytopathology, CMS). There is no evidence in the literature to support the establishment of a TAT limit for Pap tests. The survey results showed a wide range of laboratory TAT for Pap tests, ranging from 1 to 7 or more days, with a median TAT of 3 business days. Turnaround time is best used as an internal measure to assess the workflow in gynecologic cytology rather than as a benchmark for interlaboratory comparison.

Most consensus conference participants agreed that individual laboratories should determine how to measure or define TAT (Table 16, statement 3). The most common measurement of TAT starts with date/time of accessioning and ends with report sign-out. A minority of laboratories use different definitions of TAT, and this should not pose a problem, since the measurement is largely used for internal assessments. There was strong agreement that individual laboratories should determine the frequency of TAT monitoring and the metric to determine TAT variance (Table 16, statements 4 and 5). The needs for TAT monitoring may vary

by differences in individual laboratories, especially given differences in laboratory information systems.

COMMENT

The good laboratory practice statements presented herein have a range of consensus agreement or even disagreement, reflecting differences in opinion and practice patterns of consensus conference attendees. While there are many strengths of this process, there are also shortcomings to the methodology of this process. This process was not a prospective study, but a survey of practice patterns and of opinions from working group members and consensus conference attendees. However, it would be difficult to construct a prospective study of the numerous good practice statements set forth in this survey, and many of the quality monitors in this survey are mandated by regulations from CLIA or accreditation criteria by CAP and other agencies. While literature was reviewed and cited when possible, the literature was not formally evaluated for strength of evidence. Not infrequently, however, there was a dearth of literature on certain quality topics, such as monitoring of concordance between cytotechnologist and pathologist interpretations of Pap tests before sign-out.

The working group authors and consensus conference attendees were sensitive to the weaknesses and strengths of this process. The good laboratory practice statements were often crafted to not be proscriptive given the limitations of this survey process and the vast differences among many cytopathology laboratories. Indeed, the revisions to some of the good laboratory practice statements noted above reflect this struggle. The objective of these laboratory practice statements are not to proscribe a regulated quality assurance program, but rather to frame both areas of agreement and disagreement so that cytopathology laboratories may choose quality metrics, in addition to those mandated by regulations, that may be suited to their particular practice. In cases of metrics proscribed by CLIA regulations, the survey process can highlight methods that may make the use of these metrics more meaningful to the daily operation of the laboratory.

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