Good Laboratory Practices in Gynecologic Cytopathology

Joseph A. Tworek, M.D.

Background

- **CAP awarded cooperative agreement from CDC to**
  - Develop an inventory of current practices in gynecologic cytology laboratories
  - Attempt to standardize procedures for quality improvement
- **Changes since CLIA '88**
  - Proficiency testing
  - Liquid based methods with HPV testing
  - Computer assisted screening

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Multi-Step Process

- **Survey of QA practices sent to every Laboratory enrolled gynecologic PT**
- **Formation of working groups to analyze data collection**
  - **5 pathologists, 1 cytotechnologist and 1 CAP staff**
- **Posting additional queries on web site**
  - **Open ended questions**
  - **Open to cytology community**
- **Convene a consensus conference**
  - **100 attendees**
  - **Open to cytology community**

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Survey

- **Sent to 1,191 labs with 541 useable anonymous responses**
- **Topics**
  - **Diagnostic rates**
  - **Prospective and retrospective rescreening**
  - **Proficiency testing**
  - **Cytologic-histologic correlation**
  - **Concurrence of cytotechnologist and pathologist**
  - **HPV rates**
  - **Turn-around-time**
  - **General quality**

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Strengths

- **541 useable responses**
- **Good Laboratory Practice Statements vetted by working groups, web site and consensus conference.**
- **Literature cited when available.**

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Weaknesses

- **Sensitivity to regulatory environment**
- **Literature review not graded on strength of evidence**
- **Literature not always available**
- **Not a prospective study but a survey**
- **How does this apply to laboratories with low volumes of Pap tests.**

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Gynecologic Consensus Conference

Working Group 1: Monitoring Interpretive Rates, Concordance of Interpretations, Turnaround Time

June 4, 2011

http://www.cap.org

v. 1

Working Group 1

- **Joseph Tworek, MD (Senior Author)**
- **Karen M. Clary, MD (Chair)**
- **R. Marshall Austin, MD**
- **Diane Davis Davey, MD**
- **Sonya Naryshkin, MD**
- **Chiara Sugrue, SCT**
- **Beth Anne Chmara, CT(ASCP), (CAP Staff)**

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Statement: It is most useful to monitor interpretive rates for cytotechnologists individually and in comparison for the entire laboratory.

- **Basis: Respondent Data and Personal Observation**
- **From the survey, strong majorities are currently monitoring all TBS categories for cytotechnologists and also for the laboratory as a whole.**

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Voting

Statement: It is most useful to monitor interpretive rates for cytotechnologists individually AND in comparison for the entire laboratory.

4. **Do you agree with the consensus statement?**
   A. *Yes* *100%*
   B. *No* -

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Statement: It is currently unclear whether or not monitoring interpretive rates for individual pathologists beyond laboratory rates as a whole is useful.

- **Basis: Respondent Data and Personal Observation**
- **Only a third of respondent laboratories monitor TBS categories for pathologists, perhaps reflecting the more varied volume and more varied case mix of cases reviewed by individual pathologists.**

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Voting

Statement: It is currently unclear whether or not monitoring interpretive rates for individual pathologists beyond laboratory rates as a whole is useful.

5. **Is monitoring interpretive rates of individual pathologists useful to you?**
   - *A. Yes 86%*
   - *B. No 13%*
   - *C. Other 1%*
6. **Is this an area that should be explored?**
   - *C. Yes 90%*
   - *D. No 3%*
   - *E. Other 6%*

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Statement: Providing Feedback of interpretive rates is important.

- **To share individual interpretive rate data laboratory-wide, de-identify individuals**
- **To privately provide personal feedback, compare overall laboratory data in comparison to individual statistics**
- **File/retain such data with other QA documents**
- **58% of respondents believe it is helpful in a quality plan that cytotechnologists and pathologists have access to their personal interpretive rates in comparison with others in the laboratory**

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Voting

Statement: Providing Feedback of interpretive rates is important.

9. **Should individual interpretive statistics be provided to cytotechnologists and pathologists as feedback?**
   A. *Yes, regularly 88%*
   B. *No, not at all 1%*
   C. *Only as a part of scheduled employee reviews 11%*

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Statement: Actively monitoring rates at which a pathologist UPGRADES a cytotechnologist interpretation prior to sign out may be a useful quality metric.

Basis: Most laboratories monitor these metrics

Table 11. Monitoring change in diagnosis

	Frequency	Percent
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

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Which upgrade rates are monitored for Cytotechnologists?

Table 12. Upgrade rates monitored for cytotechnologists (N=381)*

Cytotechnologist Diagnosis	Pathologist Diagnosis							
	ASC-US		ASC-H		LSIL		HSIL or greater	
	Freq.	Percent	Freq.	Percent	Freq.	Percent	Freq.	Percent
NILM	285	74.8	312	81.9	373	97.9	368	96.6
ASC-US	.	.	179	47.0	216	56.7	317	83.2
LSIL	.	.	169	44.4	.	.	251	65.9
ASC-H	.	.	.	.	.	.	217	57.0

** Multiple responses allowed.*

- **Changes from NILM to SIL+ are most critical**
- **Upgrades from ASC-US to HSIL also useful**
- **Upgrades from LSIL to HSIL and ASC-H to HSIL not as frequent**

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Voting

Statement: Actively monitor rates at which a pathologist UPGRADES cytotechnologist interpretations prior to sign out. Definition of upgrades should be determined by the laboratory.

Do you agree:

A. ***Yes 79.66%***
B. ***No 15.25%***
C. ***Other 3.39%***
D. ***Other 1.69%***

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Adjudicating discrepancies and Potential limitations

- **Statement: Show discrepancies of 2 degrees or more to a third person when possible before sign out.**
  - **Preferably third person should be blinded to initial result**
  - **NILM to HSIL, ASC-H, or Atypical glandular cells**
  - **This applies to both upgrades and downgrades**
  - **Survey: this is done by 61% of laboratories**
- **Small laboratories with only one technologist or pathologist may find this difficult**
- **Some LIS systems may not be able to track cytotechnologist interpretations prior to sign-out**

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Other suggestions for adjudication (continued)

- **78% of pathologists in online survey show downgrades of HSIL to another person**
- **54% show downgrades of atypical glandular cells and these lesions also problematic**
- **Consider impact on patient care, follow-up**

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Voting

Statement: Laboratories should have policies about which categories of discrepancies should be reviewed by a third individual prior to sign out.

Do you agree:

A. ***Yes 73.68%***
B. ***No 22.81%***
C. ***Other 3.51%***

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Statement: Some categories of cases benefit from routine review by 2nd person even if CLIA does not require confirmation by a pathologist.

- **Endometrial cells in women ≥ 40years, glandular cells post-hysterectomy (36-44% in online survey)**
- **Herpes: 81%**
- **Unsatisfactory cases: 59%**
- **Rationale: Impact on management, promote interobserver reproducibility, diagnostically difficult areas**

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Voting

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**
- **Glandular cells in women post hysterectomy**
- **Herpes**

Do you agree:

A. ***Yes 90.74%***

B. ***No 9.26%***

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Gynecologic Consensus Conference

Working Group 2: Prospective and Retrospective Review

June 4, 2011

Work Group 2

- Jennifer Brainard MD, FCAP, Chair
- Michael Henry MD, FCAP, Senior Author
- George Birdsong MD, FCAP
- Tarik Elsheikh MD, FCAP
- Kalyani Naik MS, SCT(ASCP)
- Margaret Neal MD, FCAP
- David Andrew Hartley CT(ASCP)^{CM}, CAP Cytotechnologist Specialist

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Working Group 2: Definitions

- **Prospective rescreen**
  - **Review, prior to sign-out, by a second cytotechnologist of a subset of Pap tests interpreted as NILM in the first cytotechnologist review**
  - **≠ Prescreen**
- **Retrospective rescreen**
  - **Review of NILM+ Pap tests that have been signed out – an example is NILM slides from the preceding 5 years in patients with current HSIL+**

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Statement: Prospective Rescreen

Justification: Survey, Literature and Expert Consensus

1. **Maximizing the number of high risk cases increases the power of this QA measure.**
2. **Labs should include all readily identifiable HR cases *in addition* to randomly selected cases.**
3. **Multiple measures should be used to identify HR cases and to remove patients who no longer meet the criteria.**
4. **If the information is available prior to sign out, positive hrHPV NILM cases from a HPV DNA Pap test should be prospectively rescreened.**

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☐Voting: Prospective Rescreening

Statement or Question	Yes (%)	No (%)
Laboratories should make an effort to maximize the number of high risk cases in their prospective rescreens and multiple measures should be used to identify these patients.	98.61	1.39
Should all readily identifiable high risk cases be included in the prospective rescreen?	89.39	10.61
Should NILM Paps from patients with concurrent positive hrHPV results be rescreened prior to sign-out?	84.48	15.52

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Statement: Retrospective Rescreen

Justification: Survey, Literature and Expert Consensus

1. **Review of UNSAT Paps in addition to NILM Paps should be included in retrospective review**
2. **Retrospective review based on surgical biopsy results when possible is suggested**
3. **The monitoring of upgrade rates are very low for pathologists (37.3% for NILM to HSIL+)**

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☐Voting: Retrospective Rescreening

Statement or Question	Yes (%)	No (%)
To maximize the power of this measure, should retrospective review based on surgical biopsy results, when possible, be performed?	87.14	12.86
Should pathologists be included when monitoring upgrade rates in a retrospective review?	86.15	13.85

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Statement: Prospective and Retrospective Rescreen

1. **Both CTs and pathologists should get feedback on upgrade/review diagnoses**
2. **It is important to monitor ASCUS/ASCH upgrades from NILM for CTs, pathologists and the laboratory**
3. **A major barrier to implementation of enhanced/additional quality measures is limited LIS functionality**

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Voting

Question	Yes (%)	No (%)
For both prospective and retrospective reviews, should upgraded diagnoses from NILM to ASC-US/ASC-H be tracked?	63.77	36.23

Additional Voting Questions	Agree	Disagree	Uncertain
For RETROSPECTIVE review, upgraded diagnoses from NILM to ASC-US should be monitored.	*39.22*	*50.98*	*9.80*
For PROSPECTIVE review, upgraded diagnoses from NILM to ASC-US should be monitored.	*60.78*	*31.37*	*5.88*

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Gynecologic Consensus Conference

Work Group 3: PAP Proficiency Testing

June 4, 2011

Working Group 3

- **Joseph Tworek, MD (Senior Author)**
- **Lydia P. Howell, MD (Chair)**
- **Ritu Nayar, MD**
- **Sana O. Tabbara, MD**
- **Barbara Winkler, MD**
- **Lynnette Savaloja, SCT**
- **Nicole E. Thomas, MPH, CT(ASCP), (CAP Staff)**

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Statement

- **For a <u>first-time</u> PT failure (CT and Path):**
  - **Re-enrollment for re-testing is a CLIA requirement and is sufficient.**
  - **No other remedial actions required, unless supported by other performance indicators.**

Justification

- Survey:
  - Re-enroll: 83% CT, 86% Path
  - Options for remedial action did not exceed 13% for CTs or 9% for Paths
  - Labs may recognize that a single failure is not a significant finding

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Justification, con't

- Testing alters performance (anxiety?)
- Almost everyone passes eventually:
  - 99.6% passed after 3 tests (2006 CAP PT)
    - *Hughes J et al. Arch Pathol Lab Med 2009; 133:279-282.*
    - *Moriarty A et al. Arch Pathol Lab Med 2009; 133: 1757-1760.*

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Voting

- **For a first-time PT failure (CT and Path):**
  - **Re-enrollment for re-testing is sufficient.**
  - **No other interventions are required, unless supported by other performance indicators.**
- **Do you agree with this statement?**
  - **A – Yes 94.44%**
  - **B – No 5.56%**

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Statement

- **Remedial action policy should <u>not</u> be applied for a passed but non-perfect test (ie, score <100%), even for multiple non-perfect test scores.**
- Justification
  - Survey:
    - *81.4% report no policy to do so*
    - *Even in 2 consecutive non-perfect exams, only 5.2% take remedial action*
  - No literature to show that a non-perfect test is a significant finding.

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Voting

- **Remedial action policy should <u>not</u> be applied for a passed but non-perfect test (ie, score <100%), even for multiple non-perfect test scores.**
- **Do you agree with this statement?**
  - **A – Yes 93.75%**
  - **B – No 6.25%**

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Statement

- **Monitoring of incorrect slide diagnoses on passed PT tests:**
  - **Discouraged from inclusion in lab PT policy**
  - **No interventions for this test finding are necessary**

- Justification
  - Survey findings
    - *This type of monitoring only done by 26% of labs.*
  - Literature
    - *Recognition that test-taking alters performance (as in statement #3).*
    - *No literature to show that incorrect results are a significant finding.*

Voting

- **Monitoring of incorrect slide diagnoses on passed PT tests:**
  - **Discouraged from inclusion in lab PT policy**
  - **No interventions for this test finding are necessary**
- **Do you agree with this statement?**
  - **A – Yes 76.56%**
  - **B – No 23.44%**

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Gynecologic Consensus Conference

Working Group 4: Cytologic-Histologic Correlations-Summary of Consensus Conference

June 4, 2011

Working Group 4 Members

- Barbara A Crothers, DO FCAP, Chair
- Bruce A Jones, MD FCAP, Senior Author
- Leigh Ann Cahill, CT (ASCP)[CMIAC]
- Ann T Moriarty, MD FCAP
- Dina R Mody, MD FCAP
- William D Tench, MD FCAP
- Rhona J Souers, MS, CAP Biostatistician

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Statement

Laboratories should define their cytologic-histologic correlation (CHC) process to address quality issues and account for population variables. CHC benefits from a multilayered approach, employing several processes and metric measurements.

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Evidence

- **CHC cited as most valuable QA measure on survey**
  - ***4.2 out of 5 points***
  - **94% actively monitor the correlation between Pap test and biopsy results (Survey Statistics)**

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Multilayered Approach to CHC

- **Multilayered, laboratory-directed approach "drills down" in potential problem areas and can be tailored to laboratory size, issues and practice**
- **Additional QA monitors may be continuous or interval efforts**
  - **Interval efforts may target specific pairs for a pre-defined period (i.e., quarterly) to acquire a "snapshot" of laboratory performance for that indicator**
  - **Continuous efforts may be desirable for laboratories with high personnel turn-over, disruptive environments, or mitigating variables outside of the laboratory's control**
- **Justification: Professional opinion, survey, literature**

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Dual Role of CHC

- **“Real Time” correlation- review of slides prior to issue of biopsy report**
  - **Provides critical information for patient follow-up**
  - **Resolves/confirms discrepancies**
  - **Timely report to healthcare providers**
- **“Retrospective” correlation- review of slides after issuance of both reports**
  - **Monitor performance and processes of cytology and biopsy for laboratory quality improvement**

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Voting

- **88% support lab-defined CHC**
- **97% state that a multi-layered approach to CHC, suited to laboratory size and staffing, optimizes opportunities for quality improvement.**

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CHC Statement

The correlation interval between the Pap test and the biopsy should preferably be within 3-4 months, but no greater than 6 months.

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Voting

The correlation interval between the Pap test and the biopsy should preferably be within 3-4 months, but no greater than 6 months.

Consensus conference vote:

- **89% agree as stated**

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CHC Statement

Standardization of metrics and CHC process is desirable. The PPV of a positive Pap test is the preferred standard CHC metric.

- Allows for interlaboratory comparison

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Voting Summary

Consensus conference vote:

- **94% in favor of standardized metrics and CHC process**
- **70% agree that PPV is the best metric**
- **66% agree laboratories should use PPV to develop other QA metrics**

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Recommendations

Monitor:

- **Total number of CHC pairs**
- **Number of positive correlations ("true positive," as defined prior to review)**
- **Number of negative correlations ("false positive," as defined prior to review)**

- **Calculate Positive Predictive Value (PPV) of a positive Pap test**
- **Tabulate statistics at least annually**

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Cytologic-Histologic Calculation

Screening result	Diagnosis as determined by biopsy		Metric
	Positive	*Negative*	
Positive Pap test	True positive (TP)	False positive (FP)	**TP/ TP+FP= Positive predictive value**
Negative Pap test	False negative (FN)	*True negative (TN)*	TN/ TN+FN= Negative predictive value
Metric	**TP/ TP+FN= Sensitivity**	**TN/TN+FP= Specificity**	

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Gynecologic Consensus Conference

Working Group 5: Monitoring of HPV Rates

June 4, 2011

Work Group 5

- Christine Booth MD, FCAP, Chair
- Michael Henry MD, FCAP, Senior Author
- Carol Filomena MD, FCAP
- Marilee Means PhD, SCT(ASCP)
- Patricia Wasserman MD, FCAP
- Christine Bashleben, MT(ASCP) CAP staff

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Statements: HPV Testing

Justification: Survey, Literature and Expert Consensus

1. **Laboratories should only offer high-risk HPV testing for GYN specimens.**
2. **Laboratories should encourage clinicians to consider the latest consensus guidelines in ordering high-risk HPV tests on GYN specimens.**
3. **Laboratories should be cautious in using HPV test results to change or influence cytologic interpretations.**

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Questions: HPV Testing

Statement	Yes (%)	No (%)	Unsure(%)
HR-HPV tests should be ordered by the laboratory to be used as a diagnostic test to aid in morphologic dilemmas and resolve diagnostic discrepancies.	15.2	75.8	9.1
HR-HPV results should aid in down- or upgrading of Pap test interpretations when available prior to sign-out.	8.1	83.9	8.1
It is not appropriate to offer LR-HPV testing on Pap tests.	80.6	17.1	N/A

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Statements: Monitoring HPV Rates

Justification: Survey, Literature and Expert Consensus

1. **While there is significant variability in interinstitutional HPV-positive rates in ASC-US Pap tests, monitoring the HPV-positive rate in ASC-US Pap tests is a valuable broad measure of quality.**
2. **Performance beyond 2 SD's of the mean should prompt reassessment of diagnostic criteria used in the evaluation of Pap tests and/or investigation of the prevalence of HPV positivity in the population from which the Pap tests are obtained.**

(Tworek et al, *Arch Pathol Lab Med.* 2007;131:1525–1531)

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Statements: Monitoring HPV Rates

Justification: Survey, Literature and Expert Consensus

3. **Monitoring the HPV-positive rate in other diagnostic categories such as LSIL and the comparison of these HR-HPV rates to published benchmarks is also a valuable broad measure of quality for a laboratory and possibly for individuals.**
4. **When possible, individual pathologist ASC-US/HR-HPV results should be compared to ASC-US/SIL ratios to determine potential trends in over- and under-diagnosis.**

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Questions: Monitoring HPV Rates

Statement	Yes (%)	No (%)	Unsure(%)
If possible, ASC-US/HR-HPV results should be compared to ASC-US/SIL ratios per pathologist as a general quality monitor.	58.5	18.9	22.6
ASC-US reflex HR-HPV results should be monitored to determine potential trends in accuracy of diagnoses.	71.9	18.8	9.4
HR-HPV DNA results for other diagnostic categories should be monitored to determine potential trends in accuracy of diagnoses.	32.3	50.8	15.4

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Questions

Additional Voting Question	Yes (%)	No (%)	Unsure (%)
Is it appropriate for a lab to order a HR-HPV test as a diagnostic test independent of the clinician?	**6**	***84***	***10***

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Gynecologic Consensus Conference

Working Group 3, Topic 6: General Quality

June 4, 2011

Available methods for monitoring quality data

- Historical data and national benchmarks
  - Useful for smaller labs
  - Historical data will identify trends within lab
  - Published benchmarks may identify lab drift
    - *National benchmarks not always available*

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Statement: Selected metrics should be monitored individually, as well as globally for the laboratory.

- Justification: Survey and website
- Monitoring laboratory-wide data against national benchmarks may provide a baseline to identify and stratify lab performance
  - Not valuable for labs with small numbers of primary screeners
  - Taken in context with other factors (eg, high-risk population)
- Comparing individual data to laboratory-wide data may help identify outliers
  - Retain with other QA documents

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Voting: Selected metrics should be monitored individually, as well as globally for the laboratory.

A. Agree with entire statement 95.92%

B. Only individual quality data should be monitored; no global monitoring. 0%

C. Only global laboratory monitoring; no individual monitoring. 0%

D. Disagree with entire statement (ie, quality data should not be monitored at all). 2.04%

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Statement: Results of quality metrics should be shared with individual CTs and pathologists.

- Justification: Survey
- Quality metrics should be shared with each CT and pathologist
  - From survey, 59% and 81% of labs facilitate comparison of CT to other CTs and to laboratory data respectively
  - 48% and 60% of labs facilitate comparison of pathologists to other pathologists and to laboratory data respectively
  - Table 3 page 55
- Lab mean data and/or individual data could be shared openly or privately, identified or de-identified at the discretion of the lab

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Voting: Monitoring of selected metrics for individuals should include both CTs and Pathologists

A. Agree with entire statement. 92.9%

B. Only cytotechnologist quality data should be monitored. 3.57%

C. Only pathologist quality data should be monitored. 1.79%

D. Disagree with entire statement (ie, individual quality data should not be monitored at all). 1.79%

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Voting: Results of quality metrics should be shared with individual CTs and pathologists.

A. Agree with entire statement. 98.39%

B. Quality metrics should only be shared with CTs. 1.61%

C. Quality metrics should only be shared with Paths. 0%

D. Disagree with the entire statement (ie, quality metrics should not be shared at all). 0%

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Statement: Reviewing selected cases for educational purposes is a useful quality tool.

- Justification: Survey
- Multi-head review of difficult cases ranked second most useful quality metric
- 60% of labs conduct in-house review
  - Share interesting cases
  - Review of educational program slides
  - Hone diagnostic criteria
  - Review cases identified from QA
  - Review laboratory generated study material

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Voting: Reviewing selected cases for educational purposes is a useful quality tool.

A. Strongly Agree 86.4%

B. Agree 13.6%

C. Disagree 0%

D. Strong disagree 0%

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