ASC's Workload Recommendations for Automated Pap Test Screening

Developed by the ASC Productivity and Quality Assurance in the Era of Automated Screening Task Force

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In May 2009, our Task Force was formed and assigned the following charges:

1) Research and evaluate quality assurance monitors currently available for automated screening instruments
2) Recommend quality assurance monitors for automated Pap test screening
3) Create a statement of appropriate workload and screening practices for cytologic specimens when automated screening is employed
4) Monitor emerging screening technologies and make recommendations for best practices for quality assurance and workload.
5) Interact with the Cytology and Education Technology Consortium regarding assessment of emerging screening technologies

These recommendations were approved by the ASC Executive Board on August 29, 2011. These recommendations were finalized after suggestions, revisions, and commentary from the ASC Executive Board and other professional societies including American Society for Cytotechnology (ASCT) and Papanicolaou Society of Cytology (PSC). Recommendations # 1-5 were also presented and voted upon, at the CAP/CDC gynecologic consensus conference (Chicago, June 4, 2011), and received approval (Recommendation 1: 87% yes, Recommendation 2: 97% yes, Recommendation 3: 91% yes, Recommendation 4: 72% yes, and Recommendation 5: 87% yes).

We would like to emphasize, however, that these recommendations are based upon available research and current literature pertaining only to **gynecologic specimens with image-assisted screening**. Although non-gynecologic specimens and fine needle aspirates are usually included in the cytotechnologist's workload, there is no current available data to justify modifying screening practices regarding the latter types of specimens.

Recommendations:

1. Cytotechnologists' workday should not include more than 7 hours of gynecologic (Pap test) screening in a 24 hour period, provided there are no additional duties or distractions. Based on the

available evidence that fatigue and discomfort increase over time, it is considered good practice that the above time periods apply to a 24-hour period. These recommendations are applicable only to gynecologic screening, so do not necessarily apply to non-gynecologic cytology, including immediate evaluation of adequacy of fine needle aspirates. Non- screening time of gynecologic specimens must include at least two paid mini-breaks of 15 minutes each, and a 30 minute lunch break, in an 8-hour day. Breaks constitute a complete break from microscopy work, and may NOT include other activities such as data entry, quality assurance, and non-gynecologic specimen immediate evaluation and screening. Time allotted for breaks is intended for mental and muscular rest, so it can not be "worked through". Employment for less than 8 hours must also assume non-screening time of gynecologic specimens, including breaks, prorated to the total number of hours worked. For example, a person scheduled to screen Pap tests for a 4-hour shift, should have at least one 15-minute paid break, and one 15 minute lunch break, totaling to 3 ½ hours of actual gynecologic screening, and 30 minutes of non-screening. We encourage further studies of the effects of breaks lasting different intervals on screening sensitivity.

2. Future studies examining cytotechnologist workload should use actual hours of screening rather than lesser number of hours extrapolated to 8-hour days. Assuming an 8-hour workday, workload limits should be set to allow for non-screening time inherent in the work environment, and should not assume cytotechnologists will screen for the full 8 hours. This also applies to part time employees. Non-screening time includes lunch, regular breaks from the microscope to prevent eye and muscular strain, and may include data entry, QA responsibilities, etc.

3. The current FDA workload limits for automated image-assisted screening methods, including the ThinPrep Imaging System (TIS) and the FocalPoint GS are 200 and 170 slides/day, respectively. These rates are extremely high and may be associated with significant reduction in sensitivity. Recognizing that individual cytotechnologist productivity may vary, based on recent and current available literature, we recommend that the average laboratory cytotechnologist productivity not exceed **70 slides/day** using the CMS recommendations for calculating workload (imaged slide only = 0.5 slide, full manual review = 1.0 slide, imaged + manual review = 1.5 slide). This is assuming a manual review (MR) rate of imaged slides to be at least 15-20% (see recommendation #4). For example, with a 20% MR, maximum # of slides examined per day will equal 80 slides "field of view (FOV) only" (calculated as 80 x 0.5 = **40**) PLUS 20 slides FOV+MR (calculated as 20 x 1.5= **30**). So the total # of actual slides screened in this example is **100** slides (FOV and 20% MR). This slide rate must be prorated for employment of less than 8 hours/day, based on the actual number of hours a person screens. For example, a person scheduled to screen Pap tests for a 4-hour shift should not screen more than an average of 35 slides/per that shift, using the CMS recommendations for calculating workload.

4. The percentage of imaged slides that undergo full manual review should be at least either 15%, or twice (2x) the epithelial cell abnormality (ECA) rate, whichever is greater.

5. The epithelial cell abnormality (ECA)-adjusted workload measure is a promising method for calculating and monitoring cytotechnologist workload, and can be correlated to desired laboratory screening sensitivity. This method may be especially useful in the setting of higher ECA rates. Further studies of this method are necessary before full endorsement is possible.

6. Cytotechnologist productivity and workload limits are just one aspect of a good quality assurance program in a cytology laboratory. Other quality indicators to assess cytotechnologist performance are essential. These indicators may include, but are not limited, to:

    a. Monitoring interpretive rates for all the Bethesda system (TBS) categories, including NILM and epithelial cell abnormalities (ECA), calculated per cytotechnologist individually, and in comparison to the entire laboratory.
    b. Monitoring cytotechnologist-pathologist discrepancy rates prior to sign out.
    c. Maximizing the number of high risk (HR) cases in negative rescreens (by including all readily identifiable HR cases), in addition to randomly selected cases. The 10% rescreen by itself, especially without the addition of HR cases, is a very poor QA measure. Unsatisfactory Pap tests should be included in cases selected for the 10% negative rescreen, as well.
    d. Monitoring the upgraded diagnoses from NILM to ASC-US+ for cytotechnologists in the 10% rescreen.
    e. Monitoring selected metrics individually, as well as globally for the laboratory. Monitoring laboratory-wide data against national benchmarks may provide a baseline to identify and stratify lab performance, while comparing individual data to laboratory-wide data may help identify outliers. Results should be shared with each cytotechnologist.
    f. Reviewing selected cases for educational purposes is a useful quality tool. This includes sharing of interesting cases, multi-head review of difficult cases, review of educational program slides, or review of cases identified from QA or laboratory generated study material.
    g. Cyto-histologic correlation. For standardization of the Positive Predictive Value (PPV), a positive Pap test calculation should include ASC-H, LSIL+, and AGC+ interpretations.
    h. Monitoring ASC-US reflex HR-HPV results, to determine potential trends in accuracy of diagnosis. Performance beyond 2 standard deviations (SD) 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.
    i. Calculating the false negative rate (FNR) by cytotechnologist compared with the laboratory average. Recent studies using image-based screening have shown that an ASC-US threshold is more effective in calculating the FNR than a threshold of LSIL. While FNR is not an ideal measurement for determining laboratory sensitivity, it should be calculated at the ASC-US (not LSIL) threshold, if used by the laboratory. We also emphasize the importance of carefully selecting qualified personnel for the re-screening task, in order to optimize this approach.
    j. Blinded review of known significant abnormal cases.
    k. Calculating HPV positivity rates of negative cases.

    Note: Turnaround Time (TAT) should not be used as a quality metric in evaluating cytotechnologist performance, but may be used in monitoring staffing needs and laboratory workflow. It should never be used as a means of pressuring Cytotechnologists to increase their productivity at the expense of compromising the quality of the Pap test evaluation.

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Documentation/Explanatory notes/References:

1. ***Cytotechnologists' workday should not include more than 7 hours of gynecologic (Pap test) screening in a 24 hour period, provided there are no additional duties or distractions.***

   Data suggests that most cytotechnologists have decreased screening performance over the length of the day, and that breaks away from the microscope are necessary to maintain concentration and avoid mental fatigue (1,12). It is also apparent that in some laboratories, cytotechnologists are allowed to screen Pap tests for longer than 8 hours, as long as they don't exceed the FDA imposed workload limits (TM Elsheikh, personal communication). Further studies of the effect of screening between 5 and 7 hours a day are suggested.

2. ***Future studies examining cytotechnologist workload should use actual hours of screening rather than lesser number of hours extrapolated to 8-hour days***

   The workload limits set for the original FDA TIS trial as well as the original FDA BD FocalPoint GS Imaging System trial were based on extrapolated data (2-4). Subsequent studies have consistently suggested that these limits are too high (5), and that performance begins to decrease (lower sensitivity, less accurate classification of abnormal cases) after 4 hours for most cytotechnologists (see #1 above) (1). Taken together the data suggests that extrapolation is not an acceptable method to obtain reliable workload limits.

3. ***We recommend that the <u>average laboratory</u> cytotechnologist productivity should not exceed:***

   70 slides/day using the new CMS recommendations for calculating workload (imaged slide only = 0.5 slide, full manual review = 1.0 slide, imaged + manual review = 1.5 slide). This is assuming a manual review (MR) rate of imaged slides to be at least 15-20% (see recommendation #4). For example, with a 20% MR, maximum # of slides examined per day will equal 80 slides FOV only (calculated as 80 x 0.5 = 40) <u>PLUS</u> 20 slides FOV+MR (calculated as 20 x 1.5= 30). So the total # of actual slides screened in this example is 100 slides (FOV and 20% MR).

   Data for this comes from two separate sources. First, review of studies documenting switching from manual to automated screening have shown a consistent increase in abnormality rate when workload is restricted to these values, and a consistent decrease in abnormality rate when workload exceeds these limits (6). In addition, studies examining abnormality rate when cytotechnologists are asked to increase their workload over a relatively short time period also show a consistent decrease in abnormality rate above these workloads (5, 7). We understand that rate of screening varies from hour-to-hour, screener-to-screener, and slide-to-slide. This variation is expected as the complexity of the slides examined varies and performance of the cytotechnologist changes over time (12). These recommended screening rates are, therefore, recommended for a <u>laboratory average,</u> not for an individual cytotechnologist performance.

4. ***The proportion of imaged slides that undergo full manual review should be at least either 15%, or twice (2x) the epithelial cell abnormality (ECA) rate, whichever is greater.***

This is based on the results of survey data presented by Ms. Fern Miller at the ASC National meeting in 2009. The vast majority of laboratories were manually reviewing at least 15% of their cases. Also, studies demonstrated that as workload and productivity increases, there is tendency for lower percentage of manual review performed, and decreased detection of abnormalities in the Pap test (9).

5. ***The ECA-adjusted workload measure is a promising new method for calculating and monitoring cytotechnologist workload, and can be correlated to desired laboratory screening sensitivity. This method may be especially useful in the setting of higher ECA rates. Further studies of this method are encouraged before full endorsement of this method, by this Task Force, is issued.***

   Although the ECA adjusted workload (ECA rate x actual number of slides screened, where each slide, imaged only or manually screened, is counted as one, not 0.5 or 1.5) is a relatively new quality assurance measure, it is the only measure that has been directly correlated with screening sensitivity(8). The ECA adjusted workload has been shown to directly correlate with screening sensitivity at the level of ASC-US, LSIL, and HSIL in the original FDA TIS trial, and using the same data comparing manual and automated screening in actual practice (6, 9, 10). Preliminary data suggests that a very high sensitivity (approaching 100%) for ASC-US and worst diagnoses can be achieved when the workload (using ThinPrep imaging system) is no more than 700 cases/day/ECA (70 slides screened with an ECA of 10%, expressed as 70 x 10). For an example, a laboratory with an ECA rate of 5% may allow cytotechs to screen 140 slides/day, while a laboratory with an ECA rate of 20% can only allow a maximum workload of 35 slides/day per cytotechnologist, if they wish to achieve near 100% sensitivity (8).

6. ***Cytotechnologist productivity and workload limits are just one aspect of a good quality assurance program in a cytology laboratory. Other quality indicators to assess cytotechnologist performance should be implemented.***

   These include, but not limited, to QA indicators suggested by the CAP/CDC GYN consensus conference. Although there are studies documenting the utility of these quality indicators in general, there are few which correlate these measures with screening sensitivity (11), and none (to the best of our knowledge) which correlate these measures with workload in image-assisted screening.

   These recommendations are based on the opinions of the members of the Task Force and statements of quality indicators endorsed by the Gynecologic Cytopathology Quality Consensus Conference (June, 2011).

The ASC Executive Board approved the above recommendations on August 29, 2011.

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