Determining Workload with GYN Cytology Automated Screening Devices Historical Perspective and Current Issues

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GYN CYTOLOGY WORKLOAD
HISTORICAL PERSPECTIVE

1987 Wall St. Journal article[1]

- Reported on cases of several women harmed by false negative Pap tests; selected quality parameters in the implicated labs discussed
  - Workloads ~ 200 slides/day or higher in some instances (conventional preparations, manual review)

GYN CYTOLOGY WORKLOAD
HISTORICAL PERSPECTIVE

- CLIA ’88 law passed
- 1993: Regulations enacted based on CLIA ’88
  - Maximum workload of 100 slides/24hr period
  - There was no robust data on which to base workload standard, but clearly a limit was needed

GYN CYTOLOGY WORKLOAD
HISTORICAL PERSPECTIVE

- 2003: ThinPrep Imaging System receives FDA approval
  - Maximum allowable workload varies depending on the proportion of slides that undergo full manual review vs. field of view (FOV) review only, but may be as high as 200/day if all cases were FOV review only

GYN CYTOLOGY WORKLOAD
HISTORICAL PERSPECTIVE

- 2008: BD Focal Point GS Imaging System receives FDA approval
  - Conceptually similar to TIS
- Workload data submitted from trials of both devices
  - 20 cytotechnologists screened slides for periods ranging from approximately 3 - 7.9 hours/day
  - Daily productivity (8 hrs) of cytotechnologists (CTs) calculated by extrapolation

GYN CYTOLOGY WORKLOAD
HISTORICAL PERSPECTIVE

- Impact of workload variation on clinical performance (sensitivity) for individual CTs is not provided for either device in package inserts

GYN CYTOLOGY WORKLOAD
HISTORICAL PERSPECTIVE

- FDA issues clarification of algorithm for calculating workload issued in 2010[2]
  - Confusion regarding compliance among laboratories as well as inspectors

GYN CYTOLOGY WORKLOAD vs. ACCURACY

2010:

•Elsheikh et al.[3] specifically examined impact of workload on sensitivity, and raised serious doubt about patient safety at workloads >100 slides/day with TIS

•Elsheikh et al.[4] show that performance of cytotechnologists (CTs) varies significantly at different times of the workday, and differently across CTs, raising serious doubt about the validity of extrapolations (vs. actual performance measurements) from a partial to a full day

GYN CYTOLOGY WORKLOAD vs. ACCURACY

- Imaging systems are *clearly* beneficial if workloads are not excessive
  - Increased productivity
  - Increased sensitivity, depending on workload and metric used

GYN CYTOLOGY WORKLOAD vs. ACCURACY

- Renshaw et al. [5,6,7] have developed and evaluated a new metric, the Epithelial Cell Abnormality (ECA) adjusted workload
  - May be a more appropriate metric for determining a safe workload
  - The metric appears valid (retrospectively) with data submitted for FDA approval as well as with all other published studies for which sufficient information to do the calculation is available

GYN CYTOLOGY WORKLOAD vs. ACCURACY

- ECA adjusted workload:
  - Prospective evaluation has not been published to date
  - Has not been evaluated at very high workloads
  - Has not been evaluated in very high prevalence populations
  - Best implemented with pre-screening (not common in the US, more common in other countries) instead of rescreening

IMPACT of WORKLOAD on DISEASE DETECTION Considerations Looking Forward

- Extended screening intervals place elevated importance on minimizing errors
  - (USPSTF screening guidelines)[8]
- HPV vaccine will decrease prevalence of disease
  - Detection ability of humans may decrease when prevalence of disease decreases[9,10,11]

SUMMARY

- Current package inserts do not contain information on the impact of varying the workload on sensitivity
- Recent published studies indicate that the upper ranges of allowable workloads are too high, and pose a patient safety risk due to decreased sensitivity for epithelial cell abnormalities
  - Consensus of all major cytology professional societies

SUMMARY

- Workload standards for GYN cytology automated imaging systems need to be reassessed with a focus on the impact of workload on sensitivity
  - Knowledge in this field is evolving; the regulatory mechanism for setting maximum limits should allow for justifiable changes to the limits in response to new, robust scientific information in a reasonable period of time

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