Original Article

Increasing Cytotechnologist Workload Above 100 Slides Per Day Using the ThinPrep Imaging System Leads to Significant Reductions in Screening Accuracy

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BACKGROUND: With the current and projected shortage of a cytotechnologist (CT) workforce and the desire to reduce laboratory costs, increased productivity with automated assisted primary screening has become an attractive option for many laboratories. To the best of the authors' knowledge, longitudinal studies examining the effect of increasing workload on the performance of individual CTs have not been performed previously. **METHODS:** Using the ThinPrep imaging system (TIS), the performance of 3 CTs with variable levels of experience were evaluated. Their productivity was noted to increase from an average of 87 to 118 slides per day. The analysis included comparisons of error rates, screening rates, and screening times, including a review of 22 fields of view (FOV). Poststudy interviews of the CTs were also performed. **RESULTS:** Increased workload was found to be proportional to the decreased percentage of cases that underwent full manual review (25.2% to 20.1%; $P < .001$), and decreased actual screening times (7.3 hours/day to 6.7 hours/day, and 5.0 minutes/slideto 3.7 minutes/slide). This resulted in a lower detection of total abnormal findings (10.4% to 8.3%; $P < .001$), atypical squamous cells (6.7% to 4.9%; $P < .001$), and high-grade squamous intraepithelial lesion (0.9 %to 0.7%; $P = .37$), as well as an increased false-negative fraction rate (3.8% to 7.0%; $P = .08$). **CONCLUSIONS:** The results of the current study indicate that an increased average CT workload >100 slides per day with the TIS appears to have been accomplished mostly through a reduction in the amount of time spent reviewing the 22 FOV and the percentage of cases that underwent full manual review, which resulted in a significantly reduced screening performance. ***Cancer (Cancer Cytopathol)*** **2010;118:75–82.** © *2010 American Cancer Society.*

KEYWORDS: cytopathology, gynecology, gynecologic cytology, Papanicolaou smear, sensitivity, workload, ThinPrep, location-guided screening, imaging system.

With the current and projected shortage of a cytotechnologist (CT) workforce[1] and the desire to reduce laboratory costs, increased productivity with automated assisted primary screening has become an attractive option for many laboratories. Therefore, the effectiveness of implementing image-assisted cervical screening in some pathology laboratories may be determined by productivity, which depends largely on the speed with which slides are screened. The ThinPrep (TP) technique is widely used for gynecologic cytology in the United States, and it is estimated that approximately 66% of those tests use the TP imaging system (TIS) (unpublished data).

TIS is a device approved by the US Food and Drug Administration (FDA) to assist in the primary screening of gynecologic cytology.[2] It is a fully integrated, interactive computer imaging system designed to assist CTs in the primary screening of TP slides. TIS is comprised of an image processor and automated review scopes (RS). The image processor rapidly scans and locates 22 fields of view (FOV) for every slide, based on the nuclear-to-cytoplasmic ratio, nuclear size, and nuclear staining characteristics. The CT evaluates each FOV, and may elect to sign out the case as negative if the FOV contain no abnormalities. If abnormalities are found in any of the fields, manual review of the entire glass slide would be required.[2]

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DOI: 10.1002/cncy.20065, **Received:** July 3, 2009; **Revised:** September 4, 2009; **Accepted:** September 15, 2009, **Published online** February 11, 2010 in Wiley InterScience (www.interscience.wiley.com)

In the US FDA trial, TIS was shown to significantly improve the detection of abnormal cases at the threshold of atypical squamous cells and above (ASC+), but not at higher thresholds.[2] An important part of the FDA approval of TIS was the acceptance of a higher screening limit of 200 slides per day compared with 100 slides per day for manual TP screening.[2] The data on which this decision was based were quite limited, but included CTs with "extrapolated" workload productivities as high as 320 slides per day.[3]

The current literature regarding workload, outside the TIS clinical trial, is limited, but demonstrates extremes in results ranging from no appreciable change from manual TP[4] to incredibly higher screening rates.[5] More recently, we suggested that the increased screening rates noted with TIS are associated with a significantly decreased rate of detection of high-grade squamous intraepithelial lesions (HSILs).[6] Nevertheless, to our knowledge no longitudinal studies exist to date that have evaluated CT performance at progressively increasing screening rates. In the current study, we examined the screening performance of 3 CTs who systematically had their workloads increase from an average of 87 slides per day to 118 slides per day.

MATERIALS AND METHODS

This study was conducted at PA Labs in Indianapolis, Indiana, which processes approximately 90,000 Papanicolaou (Pap) smears per year and employs 10 CTs. All Pap smears are image-assisted using the ThinPrep imaging system (TIS) (Hologic Corp [previously Cytyc Corp], Marlborough, Mass). The objective of the current study was to determine how fast CTs could screen Pap smears using TIS, without significantly reducing their accuracy. This study was performed over 8 weeks, and involved 3 CTs who screened a total of 9667 Pap smears during that time period. Individual CT workloads were assessed, including total abnormal findings (defined as the total of ASC; ASC, cannot exclude HSIL [ASC-H]; low-grade squamous intraepithelial lesion [LSIL]; LSIL cannot exclude HSIL; and HSIL; divided by all cases screened), and high-risk human papillomavirus (HPV) positivity rates associated with ASC. For the purpose of the current study, HSIL and LSIL cannot exclude HSIL were combined for statistical analysis. The 3 CTs involved in the study were chosen to represent variable ranges of experience (2.5 years, 7.5 years, and 18.5 years, respectively) and screening speeds (low, intermediate, and high, respectively). The workload was calculated for each CT using the number of gynecologic cytology slides screened divided by hours spent on actual screening (range, 6.5-7.5 hours/day; the average workday was 7.25 hours, excluding breaks). These screening times did not include lunch or personal breaks, or clerical data entry.

Routinely, in our laboratory, CTs are responsible for double-checking clinical information on the requisition sheets for each case before the initiation of screening, and ensuring that the clerk correctly entered data into the computer system. This re-check includes review of the patient name, date of birth, social security number, menstrual history, specimen type, high-risk history, and orders for reflex HPV and venereal disease testing. It is estimated that this clerical re-check occupies an average of 20 minutes per tray of 20 slides (1 minute/slide; range, 15-30 minutes/tray).[6] In addition, our CTs are encouraged to not confine their screen to the 22 FOV presented to them by TIS but, in addition, to perform a quick check outside the edges of the FOV and a quick screen for an endocervical cell component or organisms if initially absent. A full manual review of the slides is performed if the 22 FOV presented any cellular abnormalities or nuclear alterations, even if reactive changes are favored.

For the purpose of the current study, the 3 participant CTs were removed from all other laboratory duties, and their time was entirely devoted to this project. In order for our results to be comparable to the TIS clinical trial study and other published reports, the CTs did not perform any re-checks of clerical data entries. Although the study was conducted in 3 phases, the CTs were not initially aware of the 3-phase design. They were only informed of the time period (8 weeks), and that we were assessing productivity in the absence of the clerical re-checks. In phase 1 (which lasted 3 weeks), the CTs were asked to screen at their usual speed, and not change their routine screening habits. The purpose of phase 1 was to establish a baseline performance. In phase 2 (which lasted 3 weeks), CTs were encouraged to screen as fast as they could, provided they still felt safe with the increased speed (ie, they did not believe that the quality of their work was compromised). In phase 3 (which lasted 2 weeks), the CTs were asked to try to meet a certain productivity expectation (individually calculated at approximately 15% higher than their average productivity in phase 2). Although this was an arbitrary figure, we chose 15% because it represented approximately the same observed increase in productivity from phase 1 to phase 2. We also believed that these requested increases in productivity

appeared to be achievable, and were still well below those approved by the FDA or reported in some other studies. However, we emphasized to the CTs that these were productivity expectations, not a "quota" (ie, there were no mandatory minimal number of slides that they were required to screen). Again, the CTs were not asked to increase their speeds until the beginning of phases 2 and 3. They were not given any directions or suggestions regarding how to attain higher speeds, nor were there any requests made to alter their screening patterns. All Pap smears underwent 100% rescreening by the remaining CTs in the laboratory, who were not involved in the study.

Categorical data were compared using a chi-square test with 1 degree of freedom. A *P* value of .05 was considered statistically significant.

Interviews with the 3 participating CTs were conducted 4 days after the termination of the study to learn about their reactions to the study and for them to share their experience. The following questions were asked: 1) What strategies or techniques did they use to achieve and maintain increased productivity throughout the 3 phases of the study? 2) Can they perform at these accelerated speeds on a routine basis? 3) What did they perceive to be most negative about this experience? 4) What positive experience did they gain from their involvement in this study?

Table 1. Total Slides Screened During the 3 Phases of Study

	Phase 1	Phase 2	Phase 3
CT 1	953	1049	772[a]
CT 2	864	1502	1058
CT 3	978	1214	1277

CT indicates cytotechnologist.
[a]CT 1 screened significantly fewer cases in phases 2 and 3 compared with the other 2 CTs. This is mainly due to: 1) her missing 2 days of work during that time period and 2) as a result of the other 2 CTs screening faster, there were fewer cases available for her to screen.

RESULTS

The results of individual CT screening performances are summarized in Tables 1 through 5. Overall, comparing phase 1 with phase 3, there was a 32% to 37% increase in the average daily productivity (number of slides screened per day) and hourly screening rates (Table 2). The average productivity and speed of all 3 CTs was 87.8 slides per day and 12.1 slides per hour in phase 1, compared with 118.5 slides per day and 16.3 slides per hour in phase 3. There was a 12% to 25% decrease in the number of cases that underwent manual review (Table 3). With similar daily volumes, the number of hours per day that were actually spent on screening decreased by 4% to 9%, and the average screening time per slide decreased from 5.0 to 3.7 minutes (Table 4). It is interesting to note that, as CTs increased their speed in phase 3, they exhausted all Pap smears available for review before the end of their 8-hour shift. The total abnormal rate decreased by 6% to 27% (Table 5). CTs with slower mean reading speeds (CTs 1 and 2) had greater increases in speed compared with the faster reader (CT 3) (Table 2), but there were no significant differences noted based on years of experience.

Table 6 compares the combined performances of the 3 CTs in phases 1 and 3. It appears that increased CT productivity was, in part, accomplished by consistently decreasing the percentage of cases that underwent full manual review (from 25.2% to 20.1%; $P < .001$), and decreasing the actual screening time (7.3 hours/day to 6.7 hours/day). There was a decrease in the total number of abnormal cases detected (10.4% to 8.3%; $P < .001$), ASC (6.7% to 4.9%; $P < .001$), and HSIL (0.9 %to 0.7%; $P = .37$), in addition to an increase in the false-negative fraction rate (FNF) (3.8% to 7.0%; $P = .08$). If the number of missed cases is tripled using a previously published estimate of rescreening sensitivity of 30%,[7] this difference becomes highly significant ($P < .01$).

In the poststudy interviews with the 3 participating CTs, there was unanimous agreement that elimination of the clerical re-checks of the requisition form and patient information was responsible for their increased

Table 2. Average Number of Slides Screened Per Day and Hourly Screening Rates During the 3 Phases of Study

	Phase 1		Phase 2		Phase 3		% Increase Between Phases 1 to 3
	Slides/Day	Slides/Hour	Slides/Day	Slides/Hour	Slides/Day	Slides/Hour	
CT 1	79	11.3	87	12.5	110	14.9	37
CT 2	87	12	100	13.7	118	15.3	36
CT 3	98	13	121	16.6	128	18.8	32

CT indicates cytotechnologist.

Table 3. Percent of Imaged Cases That Underwent Full Manual Review During the 3 Phases of Study

	Phase 1	Phase 2	Phase 3	Absolute % Increase	Relative % Increase
CT 1	30.8	29.7	27.2	−3.6	−12
CT 2	20.4	17.3	15.2	−5.2	−25
CT 3	23.2	19.5	19.1	−4.1	−17.6

CT indicates cytotechnologist.

Table 4. Average Screening Hours Per Day and Minutes Per Slide Spent During the 3 Phases of Study

	Phase 1		Phase 2		Phase 3		Absolute % Increase	Relative % Increase
	Hours/Day	Minutes/Slide	Hours/Day	Minutes/Slide	Hours/Day	Minutes/Slide		
CT 1	7.0	5.3	6.9	4.8	6.5	4.0	−.5	−7
CT 2	7.2	5.0	7.1	4.4	6.9	3.9	−.3	−4
CT 3	7.5	4.6	7.3	3.6	6.8	3.2	−.7	−9
All CTs		5.0		4.3		3.7		

CT indicates cytotechnologist.

Table 5. Total Abnormal Rate No. (%) During the 3 Phases of Study

	Phase 1	Phase 2	Phase 3	Absolute % Increase	Relative % Increase
CT 1	99 (10.4)	127 (12.1)	76 (9.8)	−.6	−6
CT 2	78 (9.0)	120 (8.0)	82 (7.8)	−1.2	−13
CT 3	114 (11.7)	100 (8.2)	109 (8.5)	−3.2	−27

CT indicates cytotechnologist.

Table 6. Results for Screening Between Phase 1 and Phase 3, for all CTs Combined

	Phase 1 No. (%)	Phase 3 No. (%)	Absolute % Increase	Relative % Increase	*P*
No. of cases	2795	3107			
Slides/d	87.8	118.5	**30**	**34**	**.31**
Hr/d screening	7.3	6.7	**−.6**	**−8.2**	**.23**
% Slides manually screened	25.2	20.1	**−5.1**	**−20.2**	**<.001**
Total abnormal findings	291 (10.4)	300 (8.3)	**−2.1**	**−20**	**<.001**
ASC	187 (6.7)	176 (4.9)	−1.8	−27	**<.001**
ASC-HPV+	89 (47.6)	102 (58.6)	11.0	23	**.04**
LSIL	54 (1.9)	68 (1.8)	0	0	1.0
HSIL	24 (.9)	24 (.7)	−.2	−22	.37
FNF	11 (3.8)	21 (7.0)	3.2	84	.08 or <.01[a]

CTs indicates cytotechnologists; ASC, atypical squamous cells; HPV+, human papillomavirus positive; LSIL, low-grade squamous intraepithelial lesion; HSIL, high-grade squamous intraepithelial lesion; FNF, false-negative fraction rate.
[a]The value was .08 using absolute numbers; if the number of errors tripled, the value was <.01 (see Results).

productivity in phase 1, compared with our routine laboratory setting. The CTs felt very comfortable with the phase 1 speed, did not have to alter their screening habits, and could easily practice in that atmosphere on a routine basis.

Phases 2 and 3, conversely, elicited completely different reactions. Although we did not dictate a "quota" to the CTs, they established a self-imposed quota to which they adhered. The CTs appeared to use several strategies to achieve increased productivity and speed. Their review was limited to the 22 FOV, and they did not perform additional quick screens outside the edges of FOV, as we routinely do in our laboratory. They increased their threshold for atypia, and ignored subtle clues that usually

triggered them to perform full manual reviews (ie, they treated reactive changes as normal). The thresholds appeared to increase as their speeds increased. On manual review, 1 CT screened and dotted the slides on her own scope, because it was faster than the automated RS. Two CTs used a timer to maintain their pace. They ignored absent endocervical cells and organisms, and did not quickly re-check for them outside the FOV.

Several negative reactions were voiced by the CTs with regard to phases 2 and 3. They believed that their main task was to screen as many slides as possible and maintain pace and, therefore, did not consider patient care as much. This resulted in a guilty feeling, which they hated. They could not afford to share difficult cases with fellow CTs because it consumed too much time. They believed they could not screen nongynecologic specimens because it would have interrupted the momentum of Pap screening. They were screening so many cases that occasionally they could not tell if yeast detected was on the current slide or had occurred 2 slides previously. They felt mentally abused in this process, and needed frequent rests. They became unfriendly toward their coworkers, and did not want to interact with them.

Although the CTs were able to endure the later 2 phases of the study (a total of 5 weeks), they believed that they could not perform at these speeds on a routine basis. The only positive feedback expressed by them was that they had an opportunity to learn about their screening comfort zone, and became more aware of what they can and cannot do.

DISCUSSION

With increasing incentives to reduce laboratory costs and improve profitability, increased productivity with automated assisted primary screening has become an attractive option for many laboratories. Therefore, the effectiveness of implementing image-assisted cervical screening in larger pathology laboratories may depend largely on the speed with which slides are screened. Some of these laboratories are encouraging their CTs to meet designated productivity expectations, not a "quota" (ie, expectations are determined on an individual basis, and do not represent a minimum number of screened slides that are required to be achieved consistently).[8]

TIS received FDA approval in June 2003,[3] based on a 2-armed clinical trial study comparing 9950 TP slides that were initially reviewed manually and then subsequently reviewed with the imager. Four institutions and 8 CTs participated in that study, which demonstrated statistically significant increases in sensitivity for atypical squamous cells of undetermined significance (ASCUS)+ and specificity for HSIL, but no statistical improvements in detection of LSIL and HSIL.[2] Subsequent studies have demonstrated an increased detection of abnormalities by TIS, including the increased detection of LSIL and HSIL.[1,4,9-13]

However, 1 of the most striking findings of the TIS clinical trial study was not related to the increased sensitivity, but rather to increased productivity. The average daily screening rates of CTs typically doubled with TIS (range, 1.6-2.8 times).[2] Screening times included the inspection of 22 FOV with subsequent manual review of abnormal slides. Among the 8 CTs involved in the clinical trial study, average daily rates ranged from 109 to 230 slides, and low to high rates ranged from 69 to 320 slides per day.[3] That study, however, had several limitations, including small sample size and a nonroutine laboratory setting (clinical trial setting). Nevertheless, the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) workload regulations recognized the manufacturer's labeling for workload levels. The FDA and Centers for Medicare and Medicaid Services have approved a daily cytologist screening workload of up to 200 slides in no less than 8 hours, using TIS (Summary of Safety and Effectiveness Data [ThinPrep Imaging System]; Available at: http://www.fda.gov/cdrh/pdf2/P020002b.pdf. Accessed November 30, 2004.) This approved workload limit represents a 100% increase over manual TP screening, but includes time spent for the manual review of slides that is not to exceed 100 slides in an 8-hour day.

There are other major limitations associated with the TIS clinical trial study, mostly relating to calculations of workload productivity and hourly and/or daily rates. For example, the highest reported average daily production of 230 slides was calculated from a CT who screened an average of only 4.5 hours per day, but his/her productivity numbers were extrapolated to represent 8 hours of screening.[3] In addition, the reported highest daily rate of 320 slides was selected from the highest hourly rate, and then extrapolated to 8 hours.[3] Therefore, these higher productivity figures were not actually achieved by any of the CTs in that study, but rather were based on extrapolated figures.

Outside the TIS clinical trial, the current literature regarding workloads in gynecologic cytology is to the best of our knowledge limited, but demonstrates extremes in results ranging from no appreciable change to incredibly

high screening rates of 2.1 minute per slide (extrapolated to 200-228 slides/7-8 hours).[4,5,14-16] The increased detection of abnormalities by TIS is largely because of its ability to detect single small cells and hyperchromatic groups, particularly when they are sparse, forcing the CT to concentrate on the interpretation of these atypical cells rather than finding them.[4] Most studies that reported significantly increased sensitivity by TIS demonstrated only modest increases in productivity and hourly and/or daily rates, which were much lower than reported in the TIS clinical trial or approved by the FDA. A review of these studies suggests that workloads of <100 slides per day are associated with increased or similar sensitivity to that of manual TP.[12] Conversely, workloads of >100 slides per day can lead to the markedly decreased detection of HSIL, and overall lower screening performance of the CTs.[5,6,12] The results from the current study are in keeping with the majority of these studies, especially those conducted in routine laboratory settings, and indicate that as workloads increase above 100 slides per day, the results of screening are significantly worse.

The results of the current study also suggest that increased TIS sensitivity is proportional to the amount of time spent reviewing the slides, and proportional to the percentage of cases than undergo full manual review. An Irish study reported that their average time per slide to review and record results from 22 FOV was 3 minutes; therefore, a batch of 20 slides was completed in 1 hour (extrapolated to 120-140 slides/7-8 hours day), but full manual review occurred in only 3% of their cases.[17] The results of the current study corroborate this finding because they demonstrate that the primary method CTs used to achieve higher screening rates was by decreasing the percentage of cases that underwent manual review. Individual data from our study also support this conclusion: for example, CT 1 had the slightest drop in manual review rate among the CTs (12% vs 25% and 17.6%, respectively), and demonstrated the smallest overall decrease in abnormal rate (6%) compared with the other CTs (13% and 27%, respectively) (Tables 3 and 5). This suggests that there may be an absolute lower limit to the number/percentage of cases that need to be manually reviewed using TIS, and warrants further investigations.

The results of the current study also demonstrate that as the workload increased, the time devoted by the CTs to screen the 22 FOV decreased (Table 4). This suggests that CTs are making their error at this initial triage stage, not at the subsequent full manual review. Roberts et al reported a TIS mean screening rate of 3.4 minutes per slide (extrapolated to 122-140 slides/7-8 hours), but found no significant gain in sensitivity or specificity at these higher speeds when compared with manual TP.[18] However, the majority of their false-negative results were because of failure by the CT at the RS to identify that abnormal changes were present in at least 1 of the 22 FOV.[18] Zhang et al reported that, after manual review, 10.5% of LSIL cases were upgraded from ASCUS and that 2.4% of initially negative results were upgraded to LSIL, and noted that the most diagnostically abnormal cells were not always present in the 22 FOV.[19] This emphasizes the importance of not rushing through the 22 FOV, and allowing sufficient time to carefully examine the FOV for any possible clues and subtle nuclear alterations.

The data from the current study indicate that the CTs appeared to struggle in identifying ASC and HSIL at higher screening rates, but were very successful in detecting LSIL. There was a marked increase in the FNF, mostly because of increased ASC and HSIL misses by the CTs (Table 6). Previous studies have shown that the cytologic features of LSIL are more reproducible, and easier to identify than HSIL.[20,21] Zhang et al reported that TIS may have limitations in detecting koilocytes in the 22 FOV, but detects abnormal cells in the majority of LSIL cases.[19] Although the decreased number of HSIL cases in the current study was not statistically significant, this likely represents a statistical limitation of the small sample size; larger studies would most likely confirm the statistical relevance of this finding. Importantly, the data from the current study suggest that CTs who miss HSIL are more likely to miss ASC than they are to miss LSIL. Therefore, in our opinion, calculating the FNF using a threshold of ASC (rather than LSIL) has a stronger correlation with potential HSIL misses, and better reflects the performance of the laboratory.

However, the current study has several limitations. First, it only involved 3 CTs. It is possible that other CTs may have different screening abilities, but to the best of our knowledge, there is no evidence of this in the literature. Second, the study was conducted over a relatively short time period. It is possible that the results would have been different if the CTs were allowed more time to adapt to the increasing workload, although again, to our knowledge there is no evidence of this in the literature. Third, because the study was performed over a relatively short time period, there was little room for the CTs to receive feedback on the quality of their performance during the study. It is possible that with additional feedback, CTs

may be able to improve their performance. Data supporting this are present in the literature, although at markedly lower workloads and using different screening methods (<50 slides/day, manual screening of routine Pap smears).[22] Finally, the CTs were aware that their cases were to undergo 100% rescreening, which perhaps contributed to less judicious screening of the slides, especially at higher rates. However, because the current study was self-funded, the majority of these limitations were largely unavoidable. A more extended time period or larger number of participating CTs would have more severely impacted the laboratory finances and turnaround times.

Finally, the poststudy interviews conducted with the participating CTs shed light on how they were able to achieve increased productivity and higher screening speeds. Their observations were corroborated by our statistical analyses. Although a "quota" was not mandated by us, the CTs apparently established self-imposed "productivity targets." This is not completely surprising, because there is often confusion among employers and employees regarding the difference between maximum workload/productivity limits versus quotas (ie, maximum screening limits may be misinterpreted or misused as productivity targets or quotas).[8] The CTs believed that their main task was to screen as many slides as possible, and some used timers to ensure that they maintained pace. They limited their review to the 22 FOV, increased their threshold for atypia, and ignored subtle clues that usually triggered them to perform a full manual review. They also experienced what they perceived to be "mental abuse," and often needed solitary mini-breaks. Socially, they became unfriendly toward their coworkers, and did not want to interact with them. They also believed that they could not perform at these higher screening rates on a routine basis. We believe that the responses from these interviews emphasize the importance of further investigating the potential emotional and social effects on CTs whenever significant increases in workload productivity are studied or considered for implementation.

In conclusion, the results of the current study demonstrated a direct correlation between the amount of time spent screening slides and the accuracy of the reading. In this prospective longitudinal study of 3 CTs who systematically increased their workload from 87 to 118 slides per day (12-16 slides/hour) using TIS, we demonstrated that higher workloads were achieved mostly by reducing the time spent examining the 22 FOV and the percentage of full manual review, which have resulted in a marked reduction in screening accuracy. There is no question that "The merger of mind and computer in the TIS" has created an improved Pap smear.[10] However, this increased accuracy can only be achieved by lower average screening rates (<100 slides/day) to allow for more careful examination of the 22 FOV.[6] Screening rates >100 slides per day proportionally cancel out the increased sensitivity gained by TIS, especially in detecting HSIL lesions.

CONFLICT OF INTEREST DISCLOSURES

The authors made no disclosures.

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