ASC Task Force Recommendations for *Productivity and Quality Assurance in the Era of Automated Screening*

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

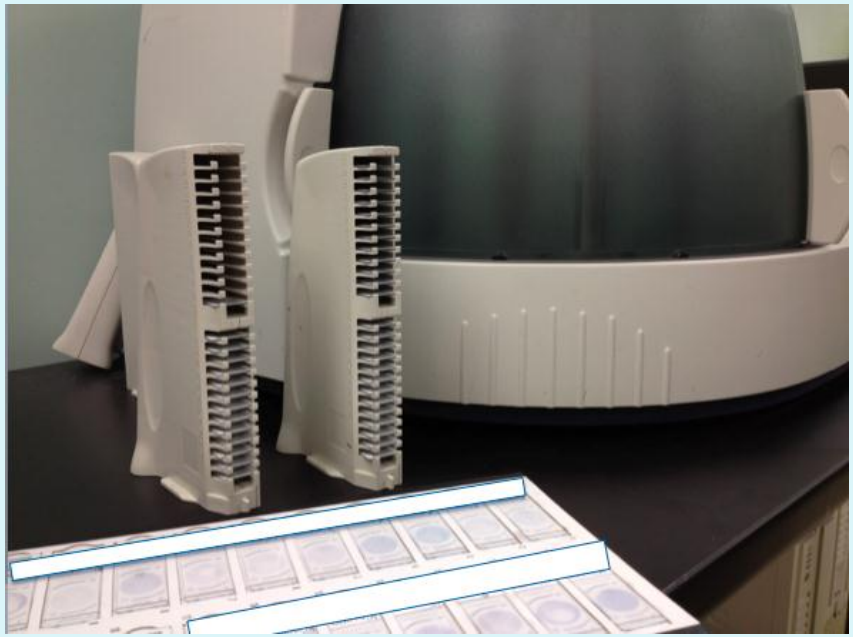
Task Force Members:

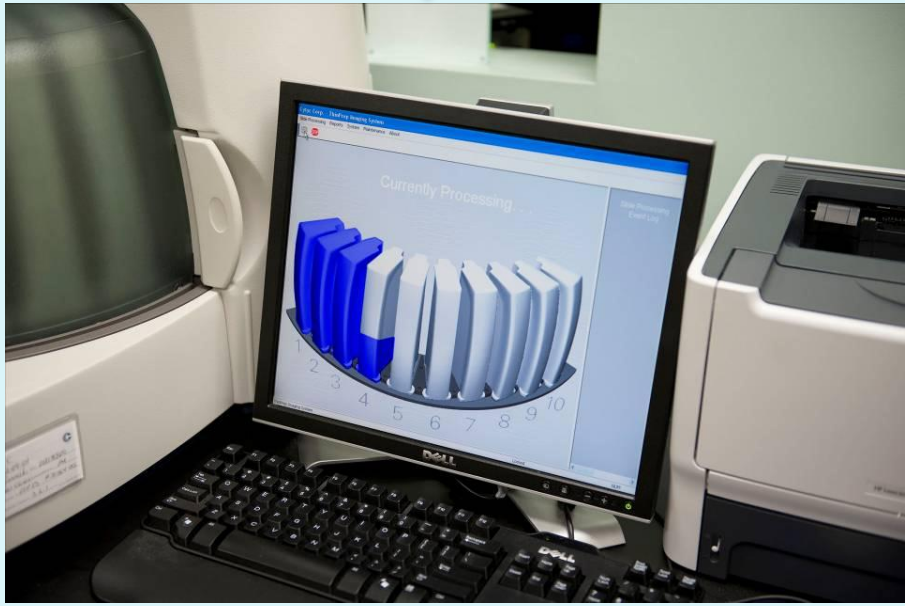
- Tarik M. Elsheikh, Chair
- Marshall Austin
- David Chhieng
- Fern Miller
- Ann Moriarty
- Andrew Renshaw

Image assisted cervical screening

- Estimated over 55 million Paps (USA)
  - 85-90% (ThinPrep and SurePath)
  - 50-65% image assisted
- ThinPrep Imaging System (TIS)
- BD FocalPoint Guiding System (FP GS)

Image Assisted Cervical Screening

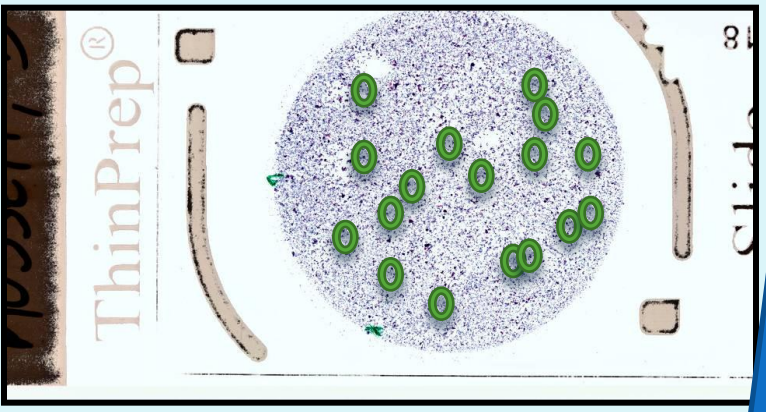


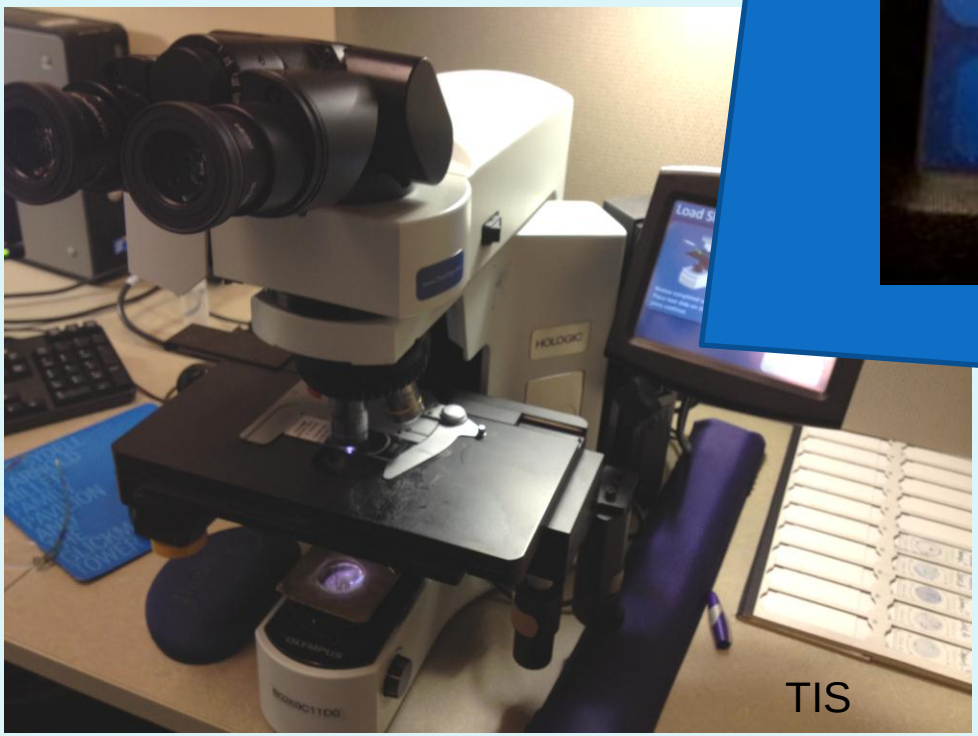


- Fully integrated interactive computer IS designed to assist cytotechnologists (CTs) in primary screening
- Image processor rapidly scans slides

TIS

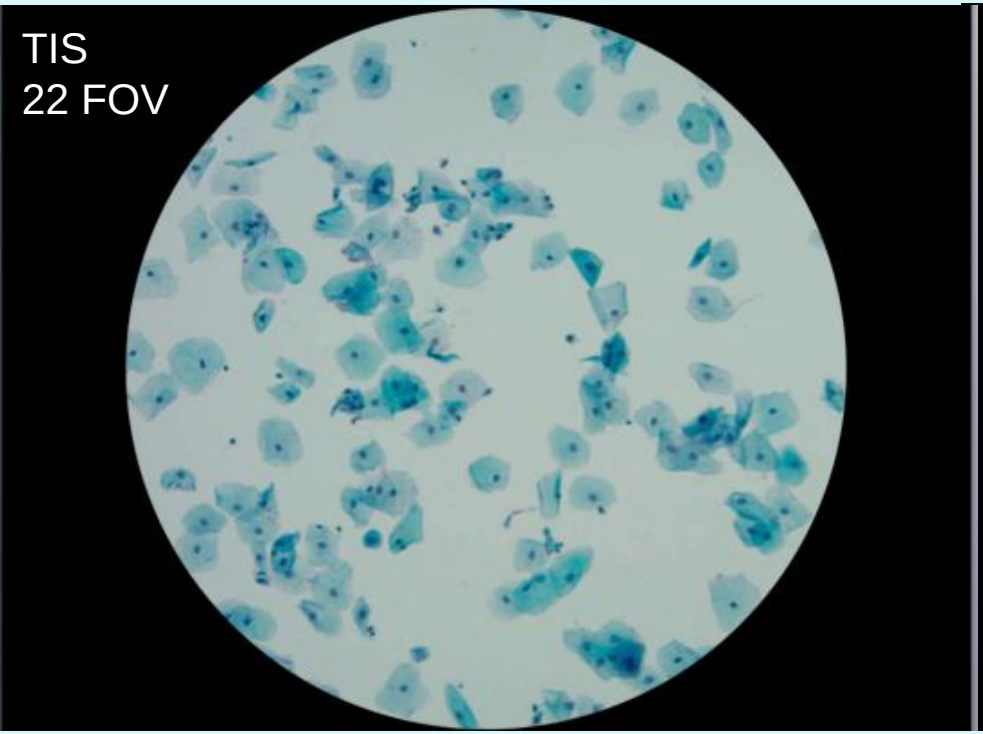
Image Assisted Cervical Screening

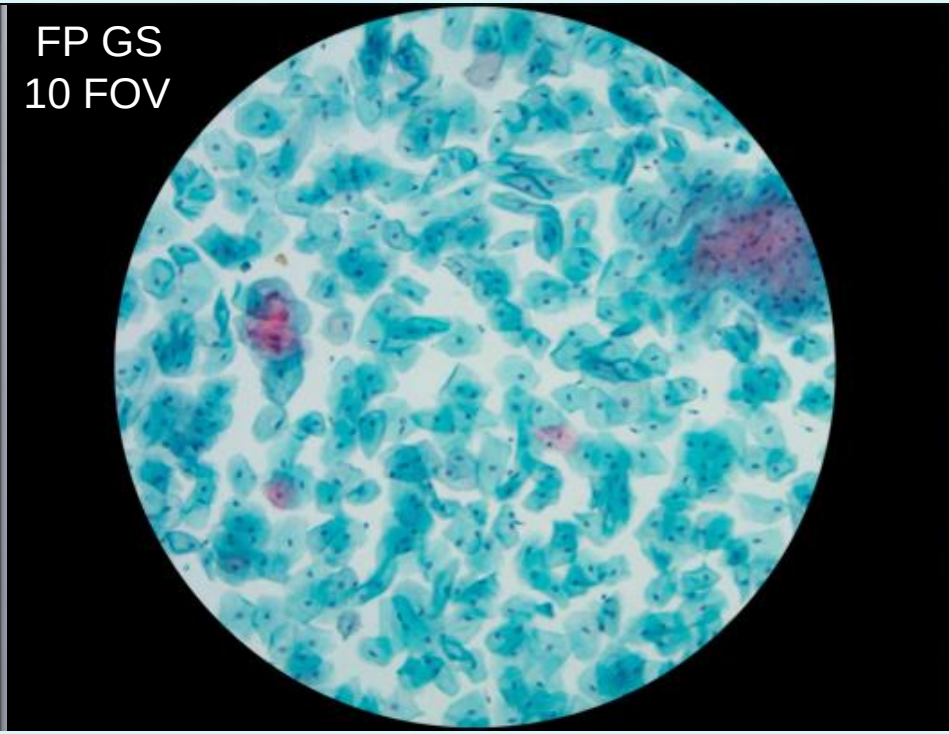




- Image processor locates 22 or 10 FOVs for every slide (TIS or FPGS)

Image Assisted Cervical Screening





- CT evaluates all FOV
  - If no abnormalities → sign out as “Negative”
  - Any abnormalities → require Full Manual Review (FMR) of entire slide

Image Assisted Cervical Screening

- Many studies showed increased sensitivity associated with imaging systems
  - Higher detection of ASC, LSIL and HSIL
- Most striking outcome is NOT increased sensitivity, but increased productivity

Halford 2010, Allen 2002, Lozano 2007, Davey 2007, Dziura 2006,Miller 2007, Pacheco 2008, Papillo 2008

Image assisted cervical screening

- FDA approved workload limits are doubled for image assisted Paps: **200 slides/day**
- **Slides counted “100” per 2010 FDA alert, as imaged only slides count as 0.5 slide**
- All workload studies, including FDA trials, counted each slide as 1.0
- Increased productivity became an attractive option for many labs

**** 2010 FDA alert:*** *"The maximum daily limit specified in each of the device product labeling is only an upper limit and should never be used as an expectation for daily productivity or as a performance target"*

- Some labs are encouraging their CTs to meet desired **productivity expectations, NOT "Quota" or "Performance Targets"**

  Expectations:

  - are determined on an individual basis
  - do not represent a minimum required # of screened slides to be achieved consistently

MLT practice guidelines 2008

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

The Task Force was 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.

May 2009

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

What represents a reasonable and realistic maximum CT workload limit, without sacrificing quality?

ASC Task Force Recommendations
September 2011

- Recommendations are based upon literature review and best available research to date
- Pertain only to **gynecologic specimens with image-assisted screening**
- Do not apply to non-GYN specimens, including FNAs

American Society of Cytopathology Task Force

Productivity and Quality Assurance in the Era of Automated Screening

Recommendations (evidence-based):

1. CT workday not include > 7 hrs of GYN screening in an 8 hr shift. Breaks should be mandatory
2. Future studies of CT workload should use actual # of screening hours
3. Average laboratory gynecologic CT workload should NOT exceed **70** slides/day (2010 FDA count)
4. Full manual review at least 15% of screened slides
5. ECA-adjusted workload: monitor CT productivity
6. Quality indicators for evaluating CT performance

September 2011

Endorsements

- ASCP (American Society of Clinical Pathology)
- ASC (American Society of Cytopathology)
- ASCT (American Society of Cytotechnology)
- PSC (Papanicolaou Society of Cytology)

UNANIMOUS

American Society of Cytopathology Task Force

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September 2011

ASC Task Force recommendations: **“The Evidence”**

- FDA clinical trial studies
  - Performed by manufactures for pre-market approval
- Literature review
- Lab survey
- Longitudinal studies
  - ThinPrep imager
  - *Focal point GS*

The FDA Clinical Trial Studies

TIS Clinical Trial

* FDA approval: 200 slides/d

- 4 sites
- 8 CTs

Table 14: Cytotechnologist Screening Rates

Site/CT	Review Methods	Total Number of Slides	Average Number of Hours	Extrapolated Daily Rates (8-hour workday)		
				Low	Average	High

Site/CT		Avg Hrs Screened Per Day	Mean Extrap Daily Rates
Site 2	Lab	**7.8**	**109**
Site 3	Lab	**4.5**	**204**
	3-1	4.2	230
	3-2	4.7	178

- 6/8 CTs screened an average of 4.2-6.1 hrs/day
- Highest CT average daily rates: 230 and 178 slides, extrapolated from 4.2 and 4.7 hrs (site 3)
- Lowest lab average daily rate: 109 slides, average 7.8 hrs (site 2)

FocalPoint GS Clinical Trial

- Total 16 CTs from 4 sites in study
  - only data from 12 CTs reported
- 5 CTs avg'd 3-4 hr
- 7 CTs avg'd 4-5 hr
- None worked > 5 hr

• All workload data extrapolated to 8 hrs
- **Highest lab avg: 150**
  - Extrap from 4.6 hr
- **Highest CT avg: 172**
  - Extrap from 4.8 hr

Table I.8.1 Cytotechnologist Screening Rates

Site/CT	Review Methods	Total Number of Slides Evaluated	Average Number of Hours Screened Per Day	Extrapolated Daily Rates (8-hour workday)		
				Low Day	Mean Day	High Day
[illegible]	MS	3,258	5.15	52.8	78.1	192.0
	GS	948	4.32	98.6	142.6	240.0

Site/CT		Avg Hrs Screened Per Day	Mean Extrap Daily Rates
Site 4	Lab	**4.61**	**150.9**
	CT 933	**4.82**	**172.2**

* FDA approval: 170 slides/ 8 hr workday

Major Limitations Associated with TIS and FocalPoint GS Clinical Trial Studies

1. Small sample sizes (9-12,000 cases)
2. Non-routine lab (clinical trial) setting
   - Screening time calculations did not include computer time, including detailed clinical information/history check or results entry into LIS
3. High day rates were extrapolated from hourly rates
4. High 8-hr daily screening rates were never actually achieved by any CT (extrapolated numbers)
5. Extrapolated rates are not realistic because they don't take into account necessary breaks or fatigue. **Cytotechnologists are not machines**

Literature Review

Image Assisted Paps and Productivity: *Literature Review*

- A major duty of cytology directors/supervisors is determining appropriate workloads for their CTs
- Literature on workload was limited
  - Entirely related to TIS
  - No FocalPoint GS studies were available, outside clinical trial
- Extremes in results:
  - No appreciable change up to >200% increase in productivity (approx 200-228 slides/day)

Lozano 2007, Schledermann 2007,Davey 2007, Duby 2009, Dawson 2006

Literature Review[2]

- No significant gain in sensitivity or specificity at higher speeds (140-160 slides/day)
- Studies that reported significant increases in sensitivity, showed only modest gains in productivity
- Workloads over 100 slides/day can lead to decreased detection of HSIL, and overall lower screening performance of the CTs

Schledermann 2007, Elsheikh 2010, Pacheco 2008

Literature Review[3]

Comparison of Manual vs. TIS Screening

3 distinct workload ranges *(all slides counted as 1.0)*

- **Low (< 60 slides/day)**
  - Workload did not influence screening accuracy
- **Intermediate (60-103 slides/day)**
  - Imager consistently increased CT detection of HSIL+
- **High (> 103 slides/day)**
  - Imager did not increase HSIL detection
  - When ASC increased, HSIL decreased: CTs tended to call abnormals as “ASC” rather than precisely classify them

Renshaw 2010

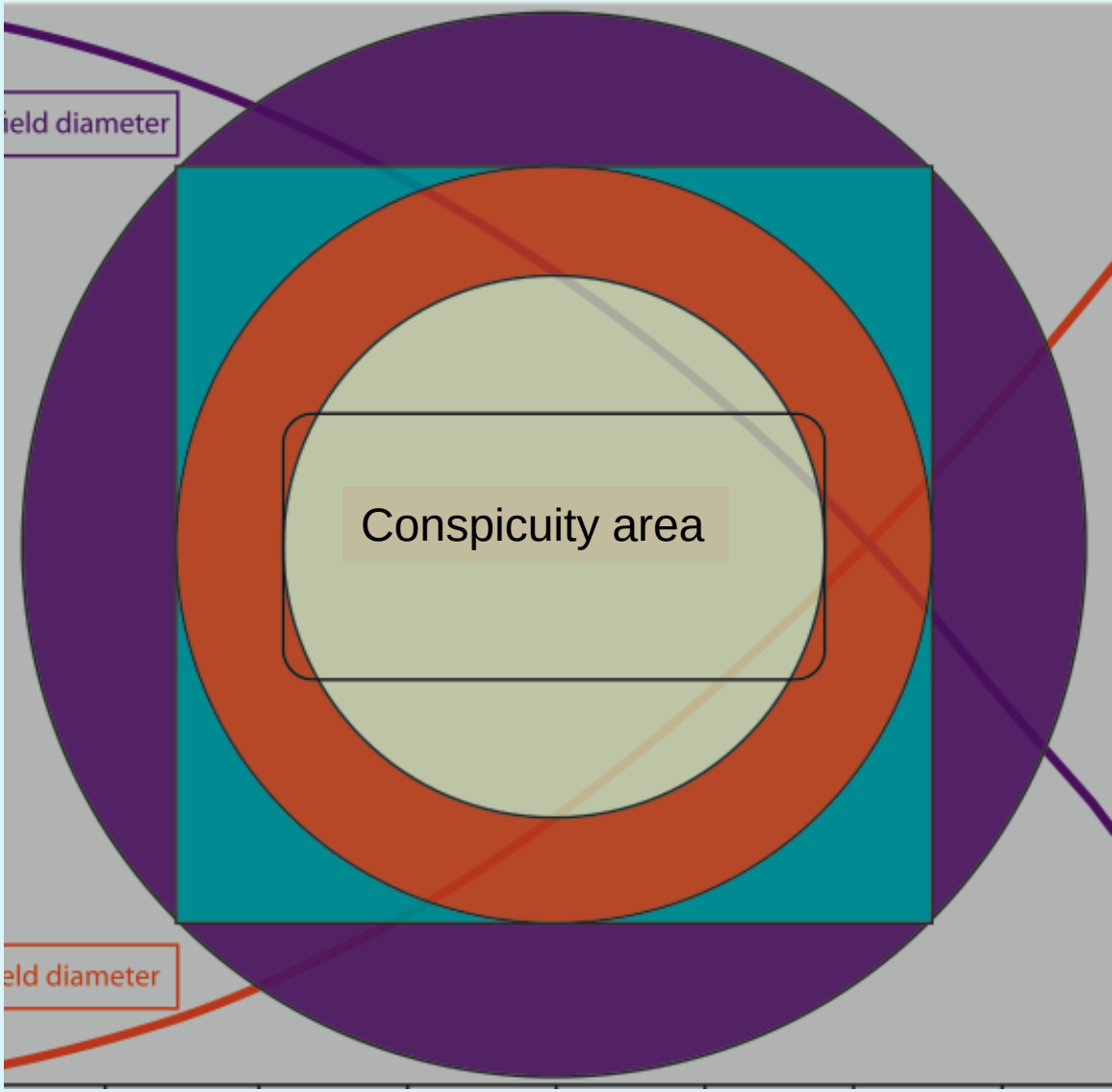
Literature Review[4]

- Increased speed was accomplished mostly by:
  - **Reduced time examining FOV** and **Lower % of Full Manual Review**
- As low as 3% FMR reported in literature
- As workload ↑ the time devoted to screen FOVs ↓
- CTs struggled to identify ASC and HSIL at higher speeds → increased misses
- Most False Negatives were due to failure to identify abnormal changes present in at least one of the FOVs

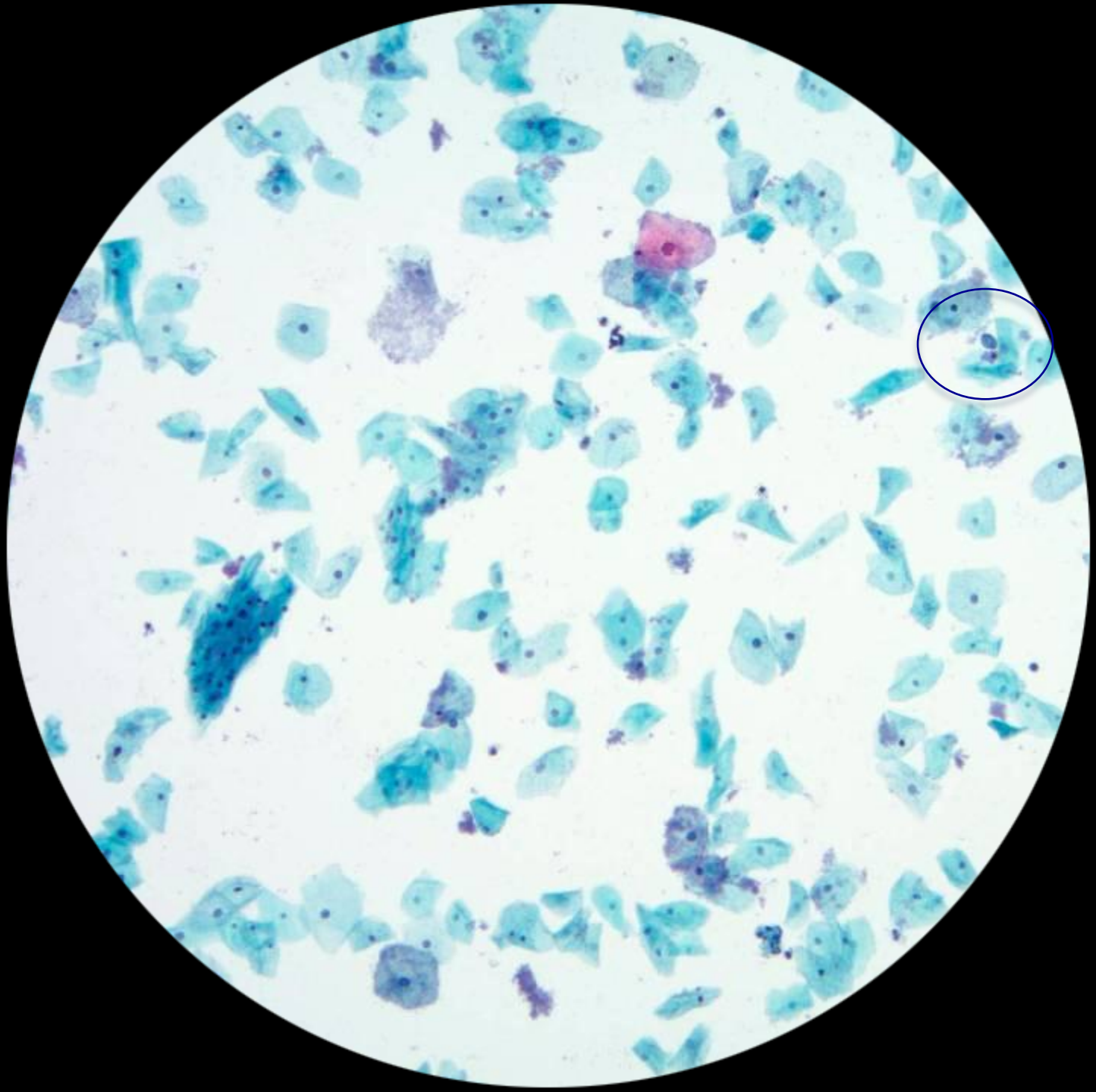
Halford 2010, Zhang 2007, Bolger 2006, Roberts 2007, Elsheikh 2010

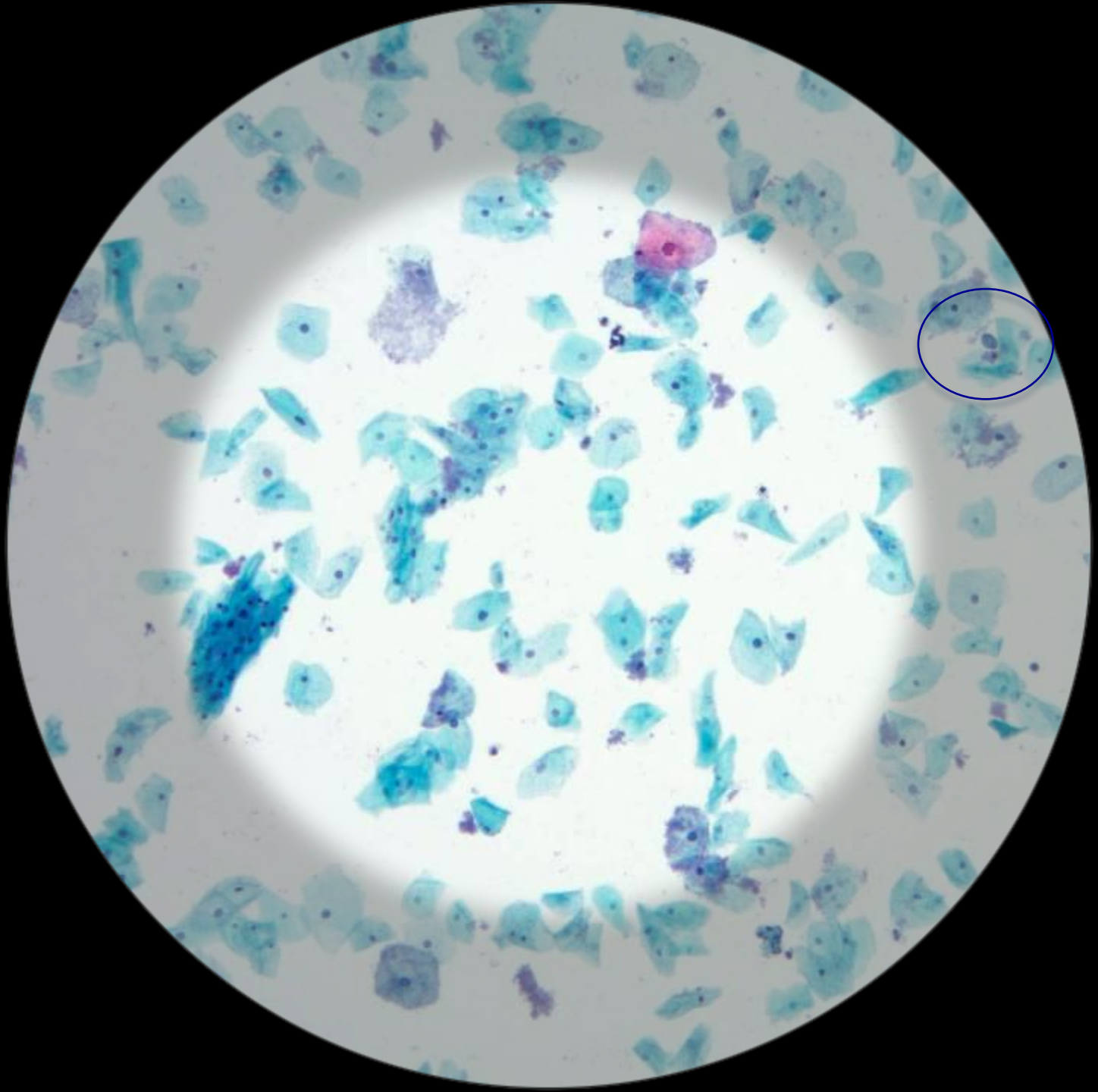
Field of View (FOV)

- Best chance to find abnormal cells is in white zone
- Likelihood worsens in **orange** zone
- Small single cells most likely missed in **purple** zone



Gill 2011





Lab Survey

Lab Survey
Image Assisted Screening

	Total Labs	Non-Hospital Labs	Hospital Labs
Labs	**31**	**18**	**13**
Techs	***312**	**224**	**88**

- Represents approx 5% of CT workforce

* No significant participation from large Commercial labs

Miller, ASC 2010

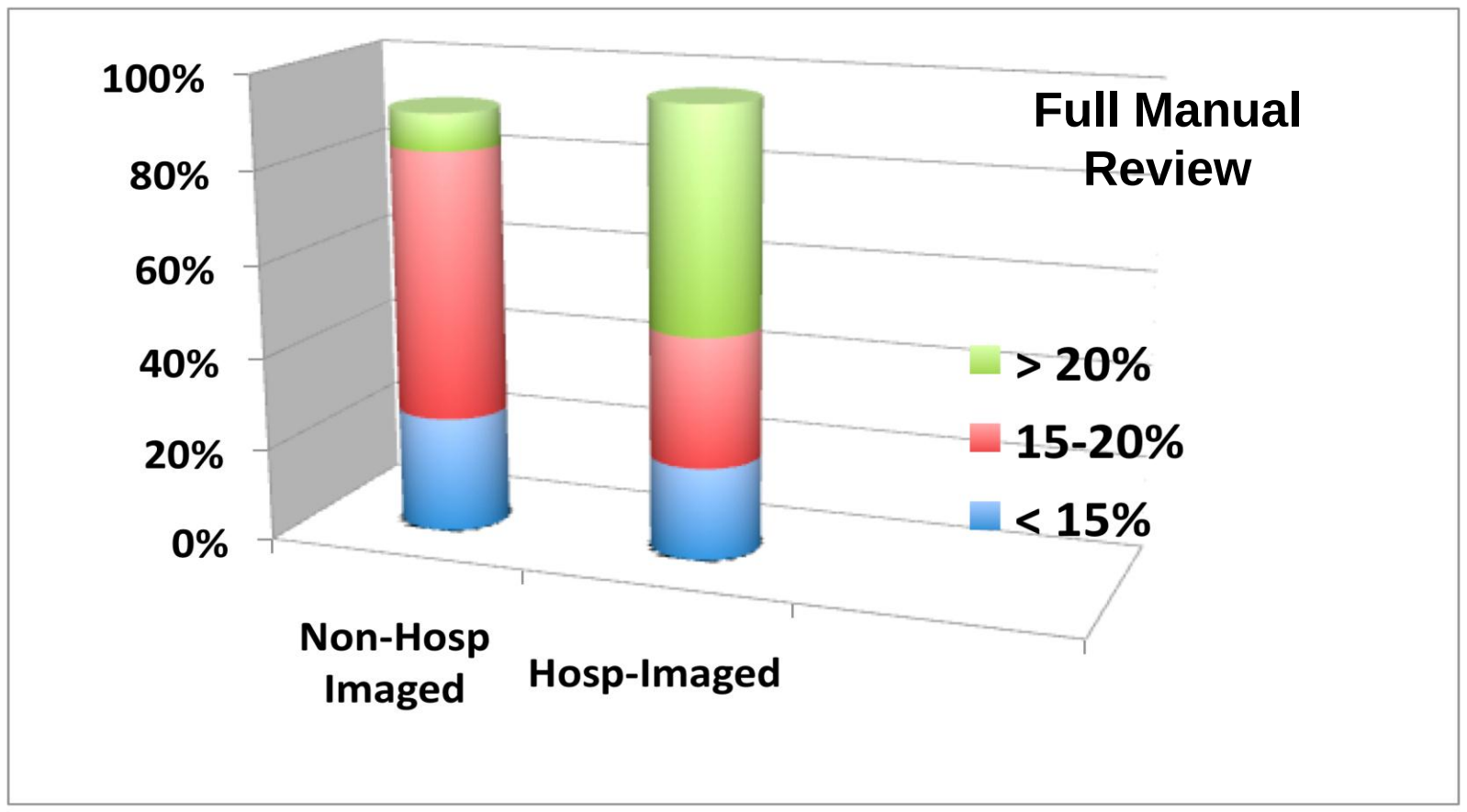
Lab Survey: Productivity with Image Assisted Screening

Slides/day	Non-Hospital Lab Average	Hospital Lab Average
	% Labs	% Labs
< 60		34%
60-80	24%	66%
81-100	34%	
101-120	30%	
121-140	12%	

- 88% of non-hospital labs screened < 120 slides/day
- 100% of hospital labs screened < 100 slides/day

Miller, ASC 2010

Lab Survey: FMR and Image Assisted Screening



- Majority of labs performed > 15% FMR
  - 25% of non-hospital labs perform < 15% FMR
  - 20% of hospital labs perform < 15% FMR

Miller, ASC 2010

Prospective Longitudinal Studies

Original Article

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

- Utilizing TIS, evaluated the performance of 3 CTs, with variable levels of experience and screening speeds
- Asked CTs to progressively increase their productivity over 3 phases (8 weeks)
- Did not specify how to increase productivity

Elsheikh 2010

	Phase 1		Phase 2		Phase 3		% increase phase 1-3
	Slides/day	Slides/hr	Slides/day	Slides/hr	Slides/day	Slides/hr	
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

- Phase 1: CTs screened at their usual pace
- Phase 2: CTs screened as fast as they could without sacrificing the quality of their work
- Phase 3: CTs screened 15% > phase 2 (individualized)
- **36% increase** in productivity: 87 to 118 slides/day (12 to 16 slides/hr) (FDA max 25 slides/hr)

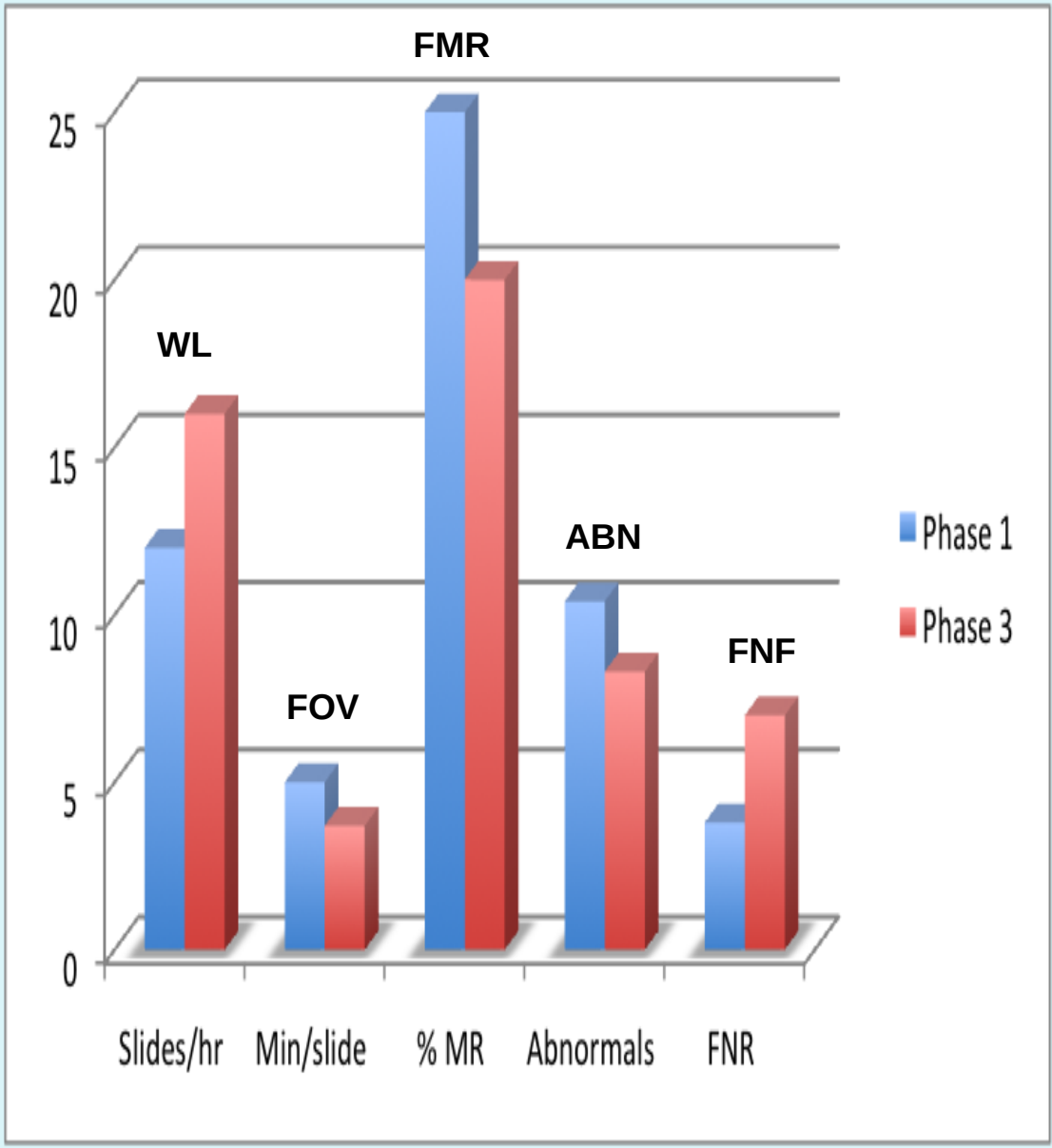
Elsheikh 2010

- We emphasized to the CTs, however, that although increased productivity was desired, they are **NOT "quota"**
  - i.e. there were no mandatory minimal # of slides required to screen, and
  - In no way should quality be compromised

Elsheikh 2010

Results

- As workload increased:
- ↓ actual screening time (FOV min/slide)
- ↓ % manual review (P <.001)
- ↓ total abnormals (P <.001), ASC, and HSIL
- ↑ FNF



Elsheikh 2010

Missed Abnormals Were For Real

	Phase 1 %	Phase 3 %	Relative %	P value
Total Abnormals	10.4	8.3	**- 20**	**< .001**
ASC	6.7	4.9	**- 27**	**< .001**
ASC-HPV+	47. 6	58.6	**+ 23**	**.04**

- ⬇ abnormal rate associated with ⬇ ASC and ⬆ ASC-HPV+ (all values statistically significant)
- Suggests higher threshold for calling atypia → under-calling Abnormals

Elsheikh 2010

FocalPoint GS Study

Design: Identical to TIS study

- 3 CTs increased their workload over 6 week period
- Phase I: CTs screened at their usual pace
- Phase II: CTs screened as fast as they could without diminishing the quality of their work
- Phase III: CTs screened 15% more than their daily workload from phase II

Levi 2011

FocalPoint GS Study

	Phase I	Phase III	% Change	*P* value
Workload Slides/day	76.7	**114.1**	**+49%**	**.008**
FOV Min/slide	5.5	3.7	**-33%**	**.031**
FMR	38%	19%	**-50%**	
Abnormals: ASC+	15.5%	10.5%	**-32%**	**<.001**
FNF	1 %	6.9%	**+60%**	**<.001**

- Overall, as CT workload increased to **>100** slides/day → ⬇ time spent/10 FOVs, ⬇ % FMR, ⬇ abnormal rate; and ⬆ FNF*(calculated at LSIL+ threshold)*

Levi 2011

Limitations of the TIS and FPGS Longitudinal Studies

- Two studies that involved only 6 CTs
  - It is possible that additional CTs may have had completely different screening abilities
    - **There is no evidence of this in the literature**
    - **CTs were carefully selected to represent good performers with varying speeds and experience**
    - **Results were reproducible at 2 different labs, with 2 different imaging systems**

Limitations of Longitudinal Studies [2]

- Studies were conducted over relatively short time periods (6-8 wks)
  - It's possible that results would've been different if:
    - CTs were allowed more time to adapt to increasing workload, or
    - By getting feedback on quality of their performance they can accordingly improve
    - **There is no evidence of this in the literature at those higher speeds**
    - **Literature shows CTs can improve their performance with feedback at much lower workloads (< 50 slides/d) & manual screening**

Brimo 2010

Limitations of Longitudinal Studies[3]

- Additional studies are needed?
  - Possibly, but
    - **Need to be evidence-based**
    - **Not based on surveys or interviews**
    - **Follow a similar model of increasing workload**
    - **These studies are very difficult to perform: most labs can not afford to have 3 or 4 CTs removed from regular duty service for several months → severe financial and TAT impacts**

THE ASC BULLETIN

PANEL DISCUSSES IMPACT OF NEW TECHNOLOGIES ON WORKLOAD LIMITS

On July 22-23, 1999, the Centers for Disease Control (CDC) convened a panel to discuss the impact of new technologies for gynecologic cytology on workload limitations. The majority of the panel members

was a divergence of opinion regarding conventional non-gyn slides due to their variable nature, i.e., fine needle aspirations that have many slides which are mostly blood.

3. **How should "workload" be defined?**

group of slides being rescreened, screening, and the use of validated commercially prepared challenge taining 40, 50, 60, 70, or 80 slide could be used as one component of

1. **The current workload limit is used inappropriately as a target in some labs.** Many participants were concerned that the 100-slide limit is too high and it was suggested that 80 slides might be more appropriate. The lack of studies correlating accuracy levels with workload was noted, and the need for such studies was stressed at several points during the meeting.

July 1999

Workload and Workday

Screening Workload

- **Clinical Practice:**
  1. Double check clinical information in laboratory information system (LIS)- excludes batch data entry
     - Patient name, DOB, SSN, menstrual Hx, specimen type, high risk Hx, orders for reflex HPV/STD testing
     - Investigate and resolve discrepancies
  2. Review FOVs
  3. Record Results in LIS

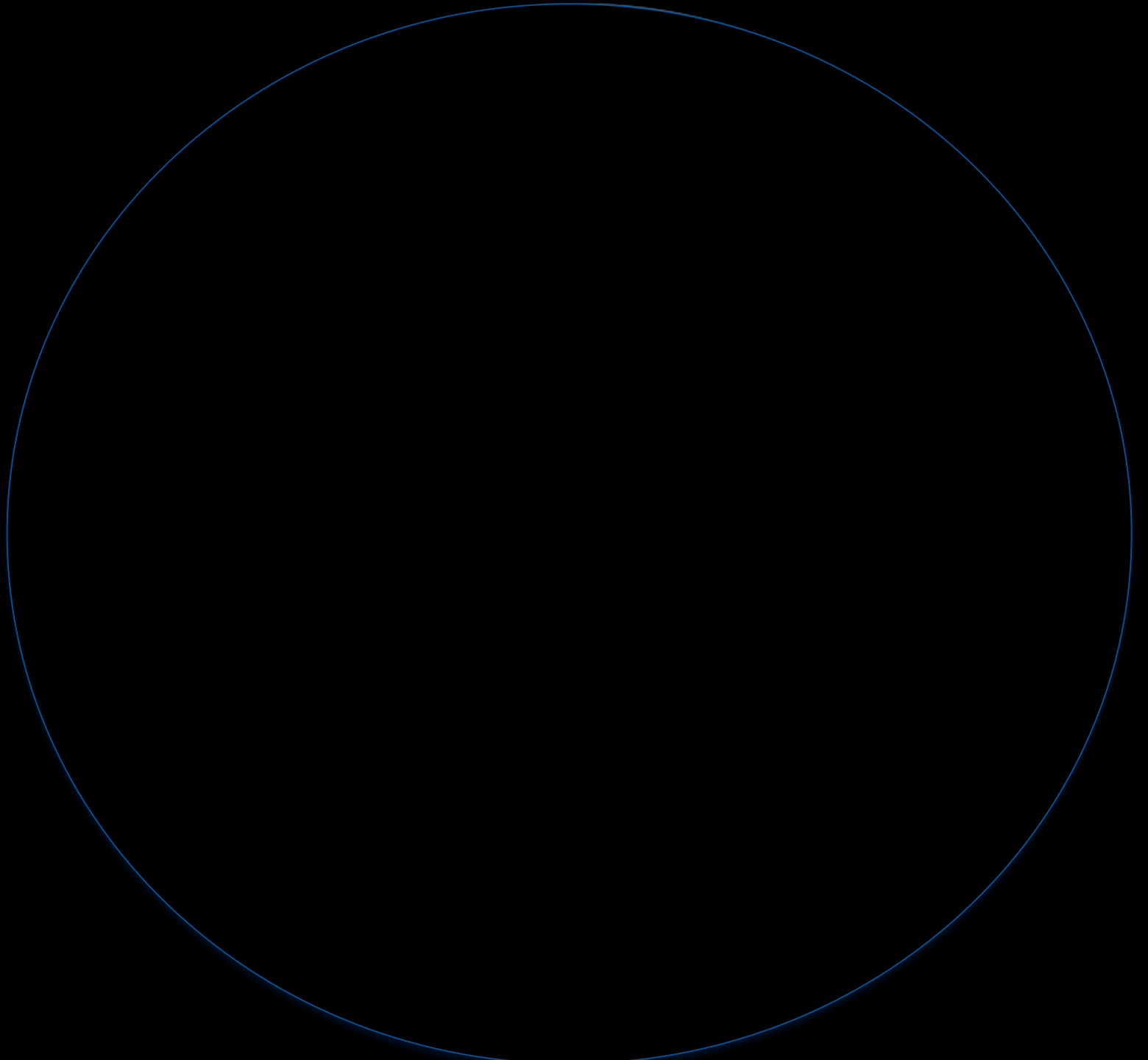
- **Research setting:**

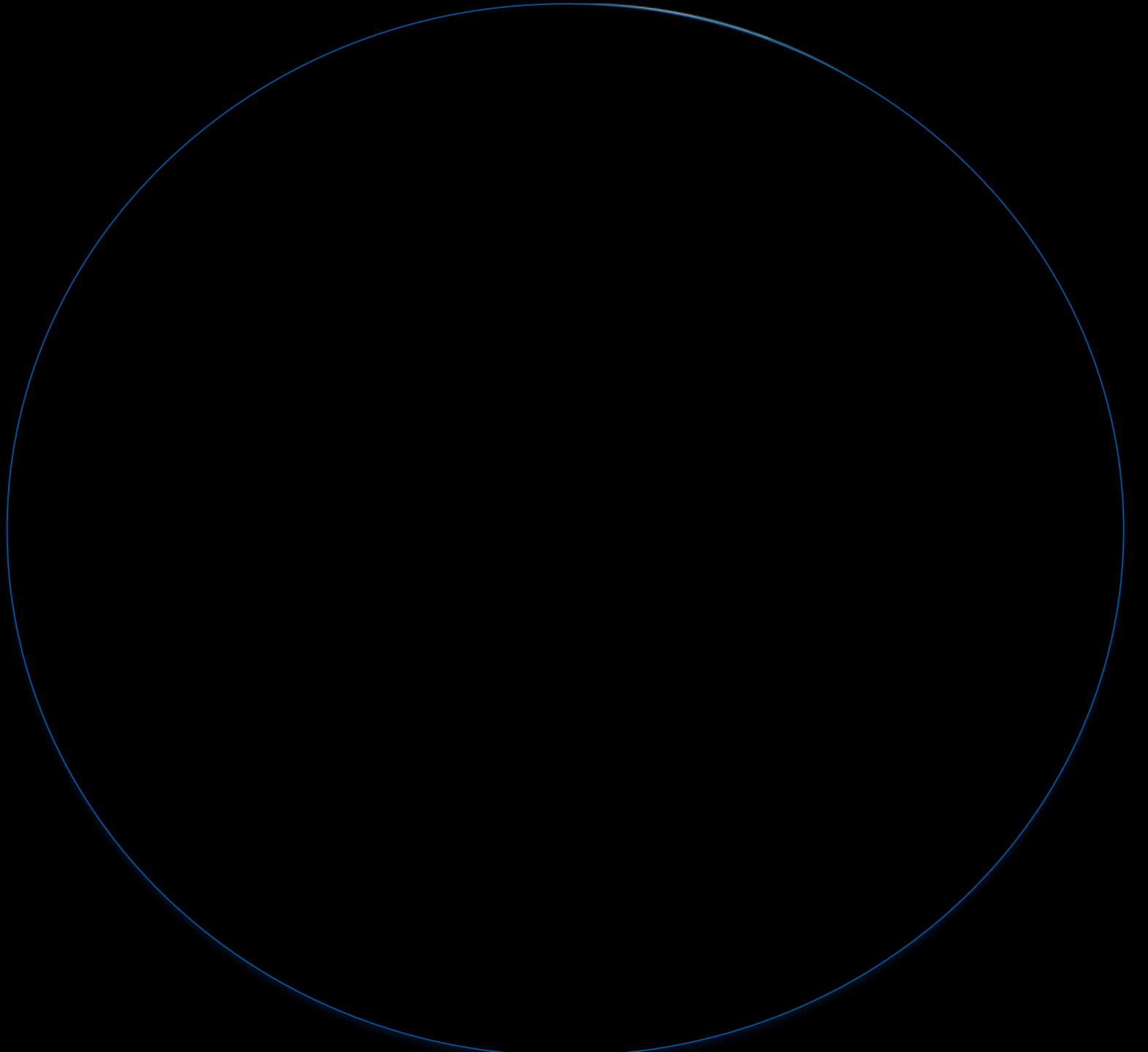
Workload studies, including FDA trials, did NOT include detailed review of clinical info/history or entry of results into LIS

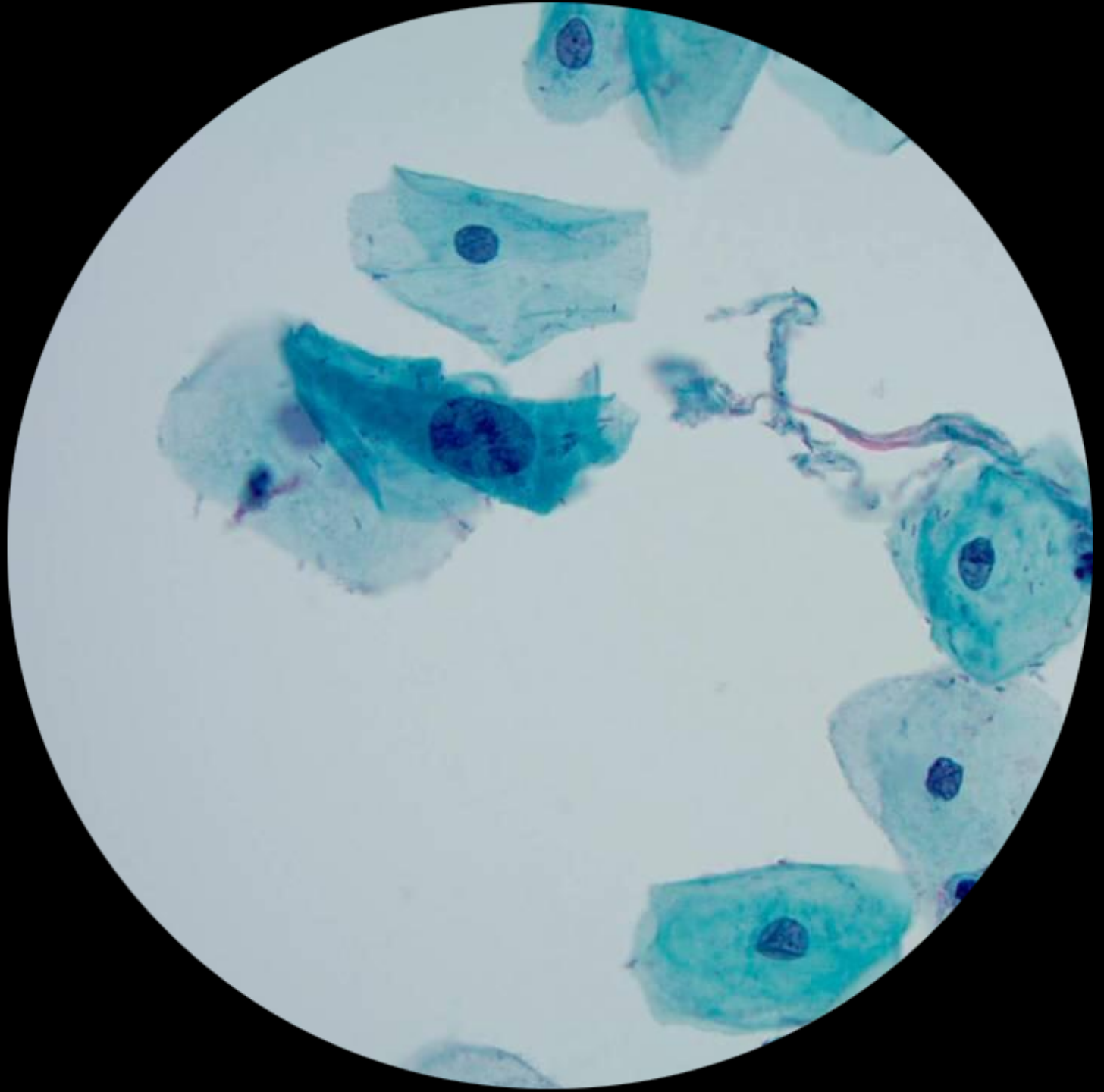
Calculation of Screening Time

- Handling & aligning slide= 48 sec/slide
- LIS time: 43 sec/slide

- Total screen time at FDA limit of 200 slide/day = 144 sec/slide
  - Non-microscopic time = 91 sec/slide
  - **FOV review = 53 sec/slide (2.4 sec/FOV)**







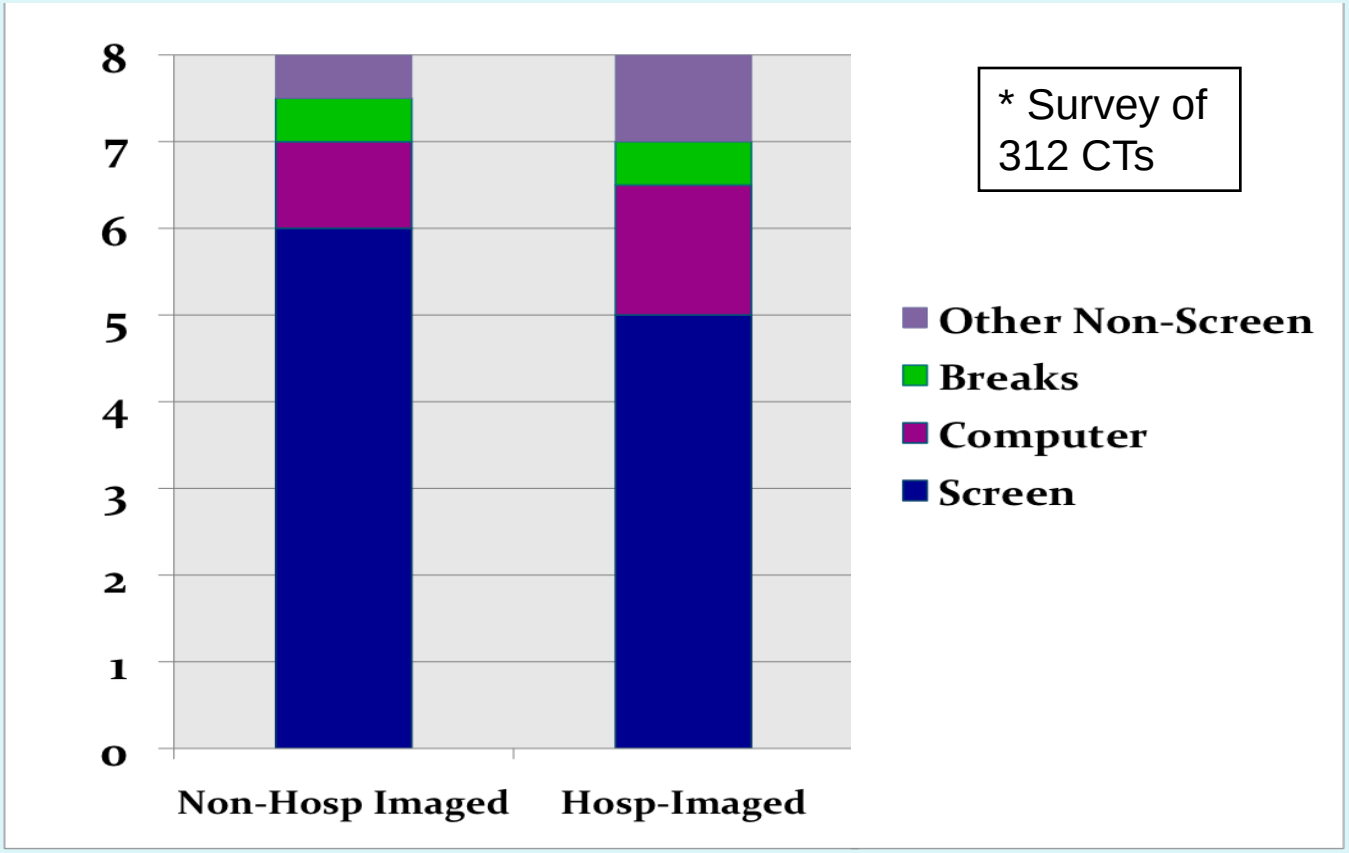
Estimated FOV times, Based on Calculating Screening Rates with and without LIS Time

	Workload rate/8 hrs		
	200 slides	150 slides	100 slides
22 FOV (1 FOV) **with LIS**	53 (**2.4**)	101 (4.6)	197 (**8.9**)
22 FOV (1 FOV) **without LIS**	96 (4.3)	144 (6.5)	240 (**10.9**)

* Time measured in seconds

** Slides counted as 1.0 not 0.5

Actual Workday- Lab Survey/Literature Review



- Computer time: 1-1.5 hrs/day
- Actual screening time: 5-6 hrs/day

- Literature: A full 8-hr shift contains closer to 6.5-7 hrs of actual screening

Davey 2007
Miller ASC 2010
Elsheikh 2010

American Society of Cytopathology Task Force

Productivity and Quality Assurance in the Era of Automated Screening

Recommendations (evidence-based):

1. CT workday not include > 7 hrs of GYN screening in an 8 hr shift. Breaks should be mandatory
2. Future studies of CT workload should use actual # of screening hours
3. Average laboratory gynecologic CT workload should NOT exceed **70** slides/day (2010 FDA count)
4. Full manual review at least 15% of screened slides
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6. Quality indicators for evaluating CT performance

September 2011

ASC Task force Recommendations
#1. Cytotechnologist Workday

- CT workday should not include more than **7** hours of GYN (Pap test) screening in a 24-hr period, provided there are no additional duties or distractions
- An 8-hr shift must include at least **2** paid breaks of 15 minutes + 30-min lunch break
- Literature:
  - Performance of most CTs decreases after 4 hrs (lower sensitivity and accuracy)
  - Breaks necessary to maintain concentration and avoid fatigue

NHSCSP publication No 14, 2003; CBWG 1997; Elsheikh 2010

ASC Task force Recommendations

#1. Cytotechnologist Workday (cont.)

- **Breaks =** complete break from microscopy
  - May NOT include other activities such as data entry, QA, non-GYN screening, or immediate evaluation
  - Time allotted for breaks is intended for mental and muscular rest, so it can not be “worked through”

ASC Task force Recommendations

#2. Future Studies of Workload

- Extrapolation is not an acceptable method for determining reliable workload limits
- Future studies examining CT workload should use actual hours of screening

ASC Task force Recommendations

#3. CT Workload Limits- Image Assisted

- FDA upper limits are extremely high and maybe associated with significant reduction in sensitivity
  - Average laboratory workload for CT should NOT exceed **70** slides/day (140 FOV only slides)

(FDA count: FOV only= 0.5, FMR=1, FOV+ FMR= 1.5)

ASC Task force Recommendations

#4. Full Manual Review

- The % of imaged slides that undergo FMR should be at least either 15% or twice (2x) the epithelial cell abnormality (ECA) rate, whichever is greater

CT Workload Limits- Image Assisted *(cont.)*

Example:

- **100** slides screened with a 20% FMR→ Calculated as follows (per 2010 FDA bulletin):

  80 slides FOV only (calculated as 80 x 0.5 = **40**)

  + 20 slides FOV+FMR (calculated as 20 x 1.5= **30**)

* Further look at developing models to help with the confusion of counting

Summary

- Minimization of the # of false negative cases, coupled with high specificity, are keys to a successful screening program
- Higher screening rates proportionally cancel out the increased sensitivity gained by imaging
- ASC task force recommendations **apply only to GYN cytology specimens**

Summary[2]

- Current maximum workloads limits for image guided screening are certainly too high for most CTs to achieve
- Workload limits should take into account microscopic screening time, LIS time, and necessary breaks; and should not be based on extrapolated numbers
- **Cytotechnologists are not machines**

"Since screening excessive # of slides may present a danger to the public, perhaps professional societies should pursue this issue with the appropriate governmental agencies"

Cytology benchmarking working group, CMLTO 1997

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