



Cytology Workload Assessment and Measure

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Cytology Workload Assessment and Time Measure

- Contract for a two-part study – ASCT Services, Inc.
 - Assessment was a survey of workload practices
 - Time measure collected screening time for image–assisted devices
 - 19/22 laboratories also participated in the survey

	Dates	# Laboratories	# Cytotechnologists
Assessment	September 27, 2013- September 26, 2014	191	369
Time Measure	September 27, 2014- February 15, 2016	22	102

Findings from Cytology Workload Assessment Survey

- 64% of the responding imaging laboratories reported using the FDA algorithm for counting workload
- 69% of the laboratories set the same workload maximum number for all cytotechnologists in the laboratory
- 73.2% of the cytotechnologists said their workload had not changed in the last two years
- The average daily number of slides screened was 76

Time Measure Study Design

Purpose:

- To measure the amount of time spent screening Pap test slides using the automated microscopes for FDA-approved image-assisted devices
 - Becton Dickinson Guided Screening System - BD
 - Hologic ThinPrep Imaging System – TIS and TIS+
- To assess the time involved to perform prescreening, screening, post screening and non screening activities **for one full workday**
 - Prescreening = **Case-set-up** (Non screening)
 - Screening = **Field of View (FOV) or FOV + Full Manual Review (FMR)**
 - Post Screening = **Case Complete** (Non screening)

Time Measure Study Design, continued

- The CT decides if there are cells on the slide that prompt them to perform a FMR.
- An observer
 - Provided training on the data collection tool
 - Oversaw the time measure
 - Reviewed slides to determine if any slides should have received a FMR and may not have received it.

Non-Screening Activities

■ Case Set Up

- Retrieve case information
- Verify patient name matches requisition
- Review patient history
- Verify billing codes
- Calibrate device
- Verify accuracy of data entry

■ Case Complete

- Enter cytology diagnosis
- Enter HPV test results
- Document workload
- Enter billing codes
- Separate and organize slides
- Deliver slides
- Verify accuracy of data entry

Screening and Other Activities

- **Screening (Microscopic)**
 - Field of View (FOV)
 - Imaged Full Manual Review (FMR)
 - Full Manual Review (FMR)

Total screening time = case set-up + FOV + FMR (if applicable) + case complete

- **Other Activities**

Other activity time =# hours worked minus total screening time

- Non-GYN or non-imaged GYN slides
- 10% rescreen/QA
- FNA, HPV or molecular
- Specimen processing
- Continuing education
- Meetings/lunch/break
- Data entry/File slides
- Digital photography

Study Participants

Device	# Cytotechnologists
Hologic ThinPrep Imaging System (TIS)	38
Hologic ThinPrep Imaging System Manual Plus (TIS+)	26
Beckton Dickinson Focal Point Glass Slide Imaging System	32
Both (TIS and BD)	6
Total	102

Average Number of Hours Spent per Activity

	Worked day of study	Total Screening Time	Performing Other Activities
TIS	8.3	4.16	4.13
TIS+	8.4	4.33	4.05
BD	8.3	4.07	4.27
Mean	8.3	4.13	4.21

Number of Slides Screened per Hour

Hourly Increment	Mean	Minimum	Maximum
1	6.3	0	21
2	10.9	0	25
3	11.0	0	22
4	11.4	0	28
5	9.3	0	25
6	10.0	0	23
7	10.4	1	21
8	9.8	1	21
9	3.9	1	15
All Hours	76	16	139

Number of Slides Screened

Range of slides screened	Number of Cytotechnologists N=99
0- 25	1
26-50	8
51-75	44
76-100	29
101-125	16
126-150	1

Comparison of Slides Receiving FMR and a Diagnosis of Atypical Squamous Cells of Undetermined Significance (ASCUS) or Higher

	% FMR	% ASCUS+
Mean	28.6	11.1
Minimum	2.0	0
Maximum	93.0	41.9
Standard Deviation	17.4	6.9

Next presentations

- Cytology Time Measurement Study Data Analysis – Thomas Taylor
- FDA Policy – Alberto Gutierrez, Ph.D.