



Analysis of Data from the Maryland Cytology Proficiency Testing Program

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Objectives

- Provide scientific basis for changes in the regulations
- Using Maryland raw data
 - ❖ Evaluate performance according to CLIA scheme
 - ❖ Compare alternate grading schemes to CLIA
 - ❖ Compare results of a simulated 20 slide test with a 10 slide test
 - ❖ Evaluate frequency of testing



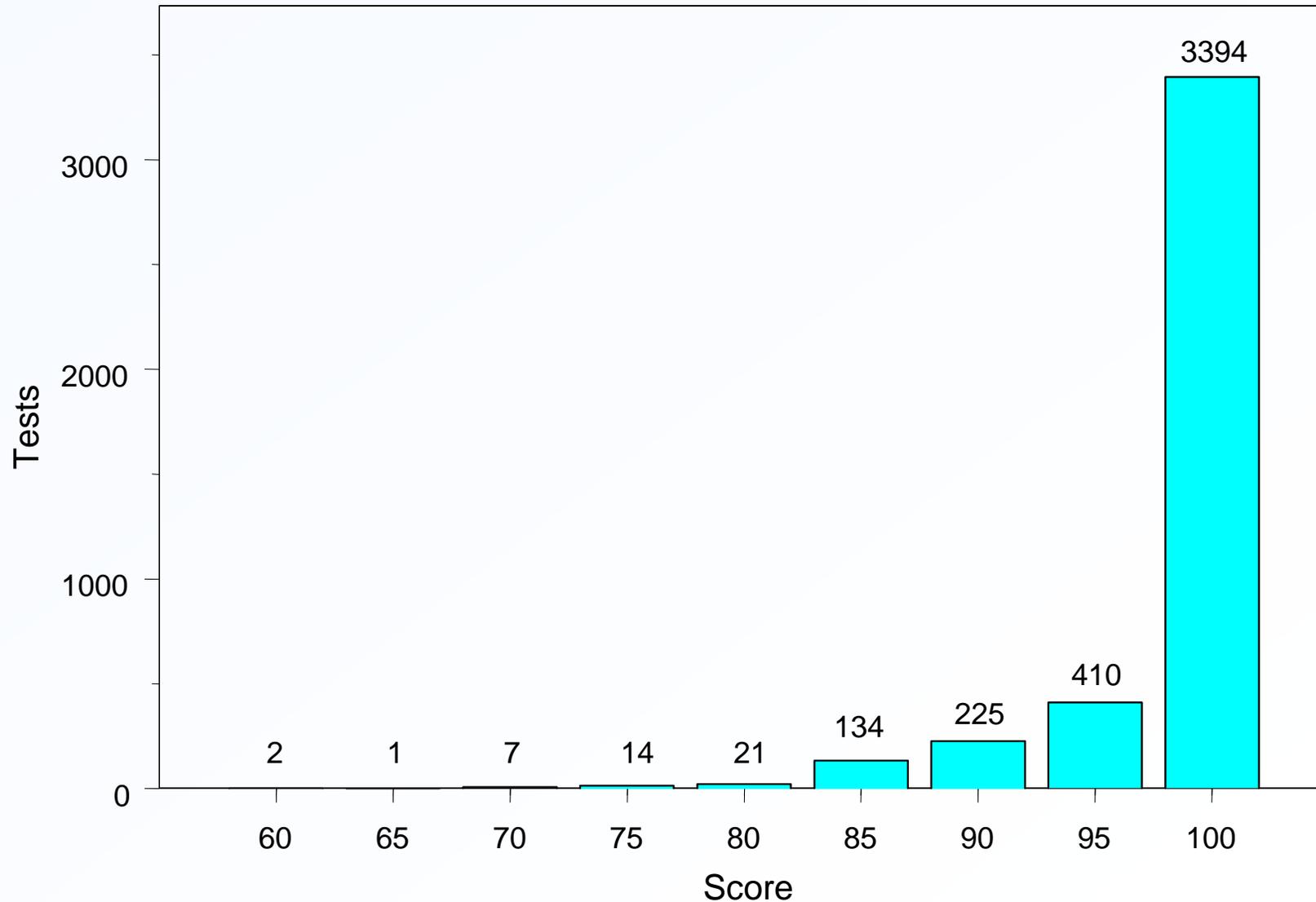
Maryland Data: Number of Individuals

- 7 Years: 1998-2004
- Total # individuals (initial test): 1261
 - CT – 869
 - MD with CT – 369
 - MD – 23
- Total # individuals (retest): 163
 - CT – 121
 - MD with CT – 36
 - MD -- 6



Distribution of Initial Test Scores

Maryland Cytology PT Frequency Distribution, N=4208 tests





CLIA Grading Scheme

Initial test and first retest

Correct Response	Pathologist (Technical Supervisor) 10-Slide Test			
	Examinee Response			
	A – UNSAT	B - NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	0	0
B – NEGATIVE	5	10	0	0
C – LSIL	5	0	10	5
D – HSIL	0	-5	5	10

Correct Response	Cytotechnologist 10-Slide Test			
	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	5	5
B – NEGATIVE	5	10	5	5
C – LSIL	5	0	10	10
D – HSIL	0	-5	10	10



Maryland Data Analysis

Key Points

Scores of <90% on initial test:

- ✓ 4.3% of total tests (179/4208)
- ✓ 8.6% of first time test takers (59/679)
- ✓ ~33% were first time test takers (59/179)

Percent not passing due to calling HSIL negative (automatic failure)

- ✓ 11.5% CTs (15/131)
- ✓ 7.3% MDs with CT (3/41)
- ✓ 0% MDs (0/7)

Failure to distinguish between LSIL and HSIL did not result in any MDs not passing



Alternative Grading Schemes Evaluation Approach

- Maryland raw data for individuals was scored using four proposed grading schemes
- Simple scoring grid, 10 points for a correct answer and 0 points for an incorrect answer added for comparison
- Percent scoring less than 90% using those models were compared to CLIA scores
 - ❖ 3 schemes suggested by the work group
 - ❖ 1 scheme proposed in the Cytology Education Technology Consortium (CETC) comment



Simple Scheme

Point values in blue italics represent a change from CLIA scoring

Correct Response	10-Slide Test			
	Examinee Response			
	A – UNSAT	B-NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	0	0
B – NEGATIVE	<i>0</i>	10	<i>0</i>	<i>0</i>
C – LSIL	<i>0</i>	0	10	<i>0</i>
D – HSIL	0	<i>0</i>	<i>0</i>	10



Proposed Grading Schemes

	separate HSIL & LSIL (MD only)	MD & CT scored differently	-5 for calling HSIL Negative	point value for calling Neg Unsat
CLIA	√	√	√	5
Model A				0
Model B				10
Model C (CETC)	√	√		10
Model D	√	√		5

√ = applies to grading scheme



Models A & B

Point values in blue italics represent a change from CLIA scoring

Model A		10-Slide Test			
Correct Response	Examinee Response				
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL	
A – UNSAT	10	0	0	0	
B – NEGATIVE	<i>0</i>	10	0	0	
C – LSIL	<i>0</i>	0	10	<i>10</i>	
D – HSIL	0	<i>0</i>	<i>10</i>	10	

Model B		10-Slide Test			
Correct Response	Examinee Response				
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL	
A – UNSAT	10	0	0	0	
B – NEGATIVE	<i>10</i>	10	0	0	
C – LSIL	5	0	10	<i>10</i>	
D – HSIL	0	<i>0</i>	<i>10</i>	10	



Model C

Point values in blue italics represent a change from CLIA scoring

Model C (CETC) Pathologist (Technical Supervisor) 10-Slide Test				
Correct Response	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	0	0
B – NEGATIVE	<i>10</i>	10	0	0
C – LSIL	5	0	10	<i>7.5</i>
D – HSIL	0	<i>0</i>	<i>7.5</i>	10

Model C (CETC) Cytotechnologist 10-Slide Test				
Correct Response	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	5	5
B – NEGATIVE	<i>10</i>	10	5	5
C – LSIL	5	0	10	10
D – HSIL	0	<i>0</i>	10	10



Model D

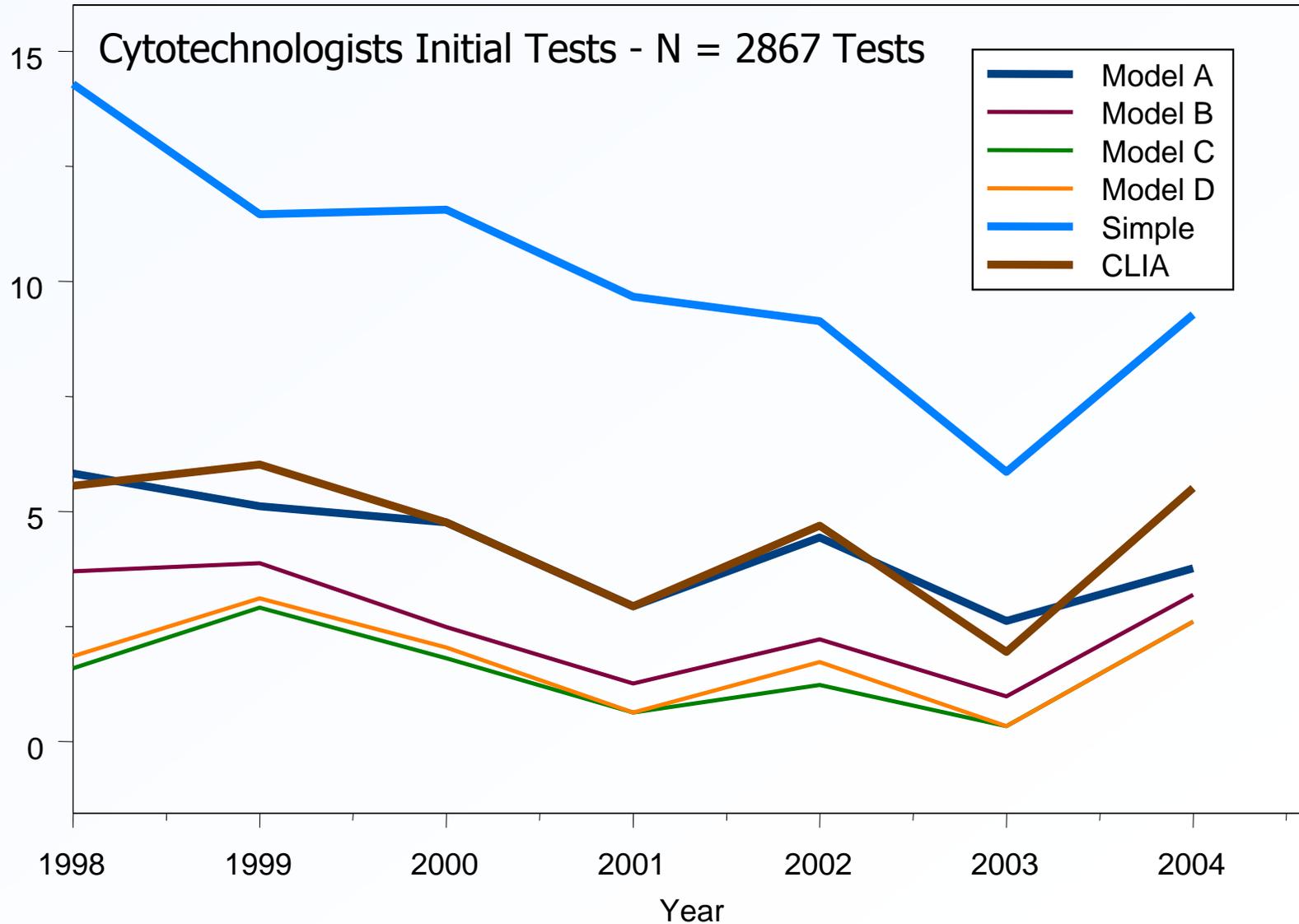
Point values in blue italics represent a change from CLIA scoring

Model D Pathologist (Technical Supervisor) 10-Slide Test				
Correct Response	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	0	0
B – NEGATIVE	5	10	0	0
C – LSIL	5	0	10	5
D – HSIL	0	<i>0</i>	5	10

Model D Cytotechnologist 10-Slide Test				
Correct Response	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	5	5
B – NEGATIVE	5	10	5	5
C – LSIL	5	0	10	10
D – HSIL	0	<i>0</i>	10	10



Grading Scheme Comparison: Percent Scoring <90%, MD Data 1998-2004





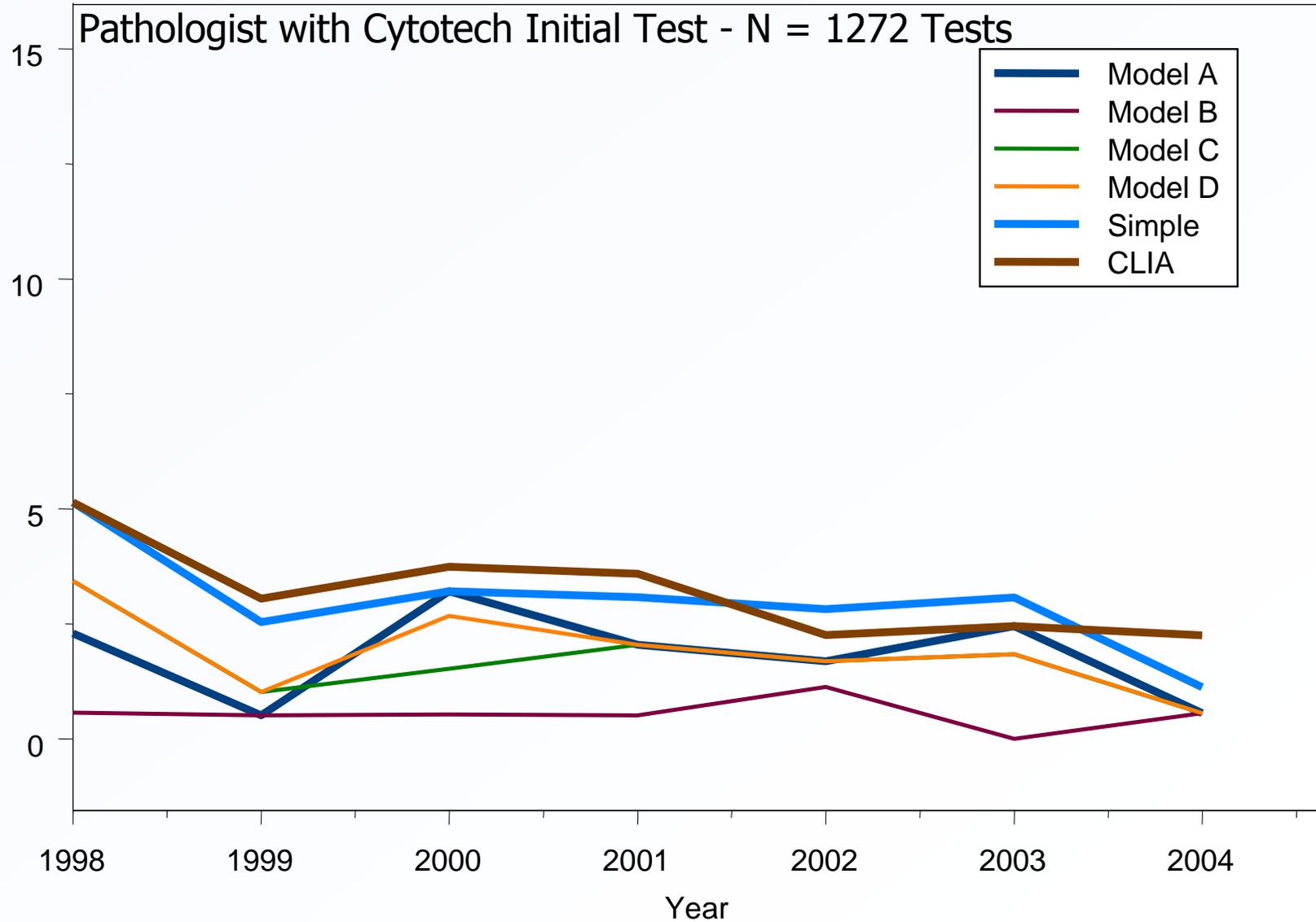
Grading Scheme Comparison

% Cytotechnologists scoring less than 90%
Initial test, 1998-2004; N=2687 tests

Grading Model	Range		Average
	Low	High	
Simple	5.9	14.3	10.2
CLIA	2.0	6.0	4.5
Model A	2.6	5.8	4.3
Model B	1.0	3.9	2.5
Model C	0.3	2.9	1.6
Model D	0.3	3.1	1.8



Grading Scheme Comparison: Percent Scoring <90%, MD Data 1998-2004





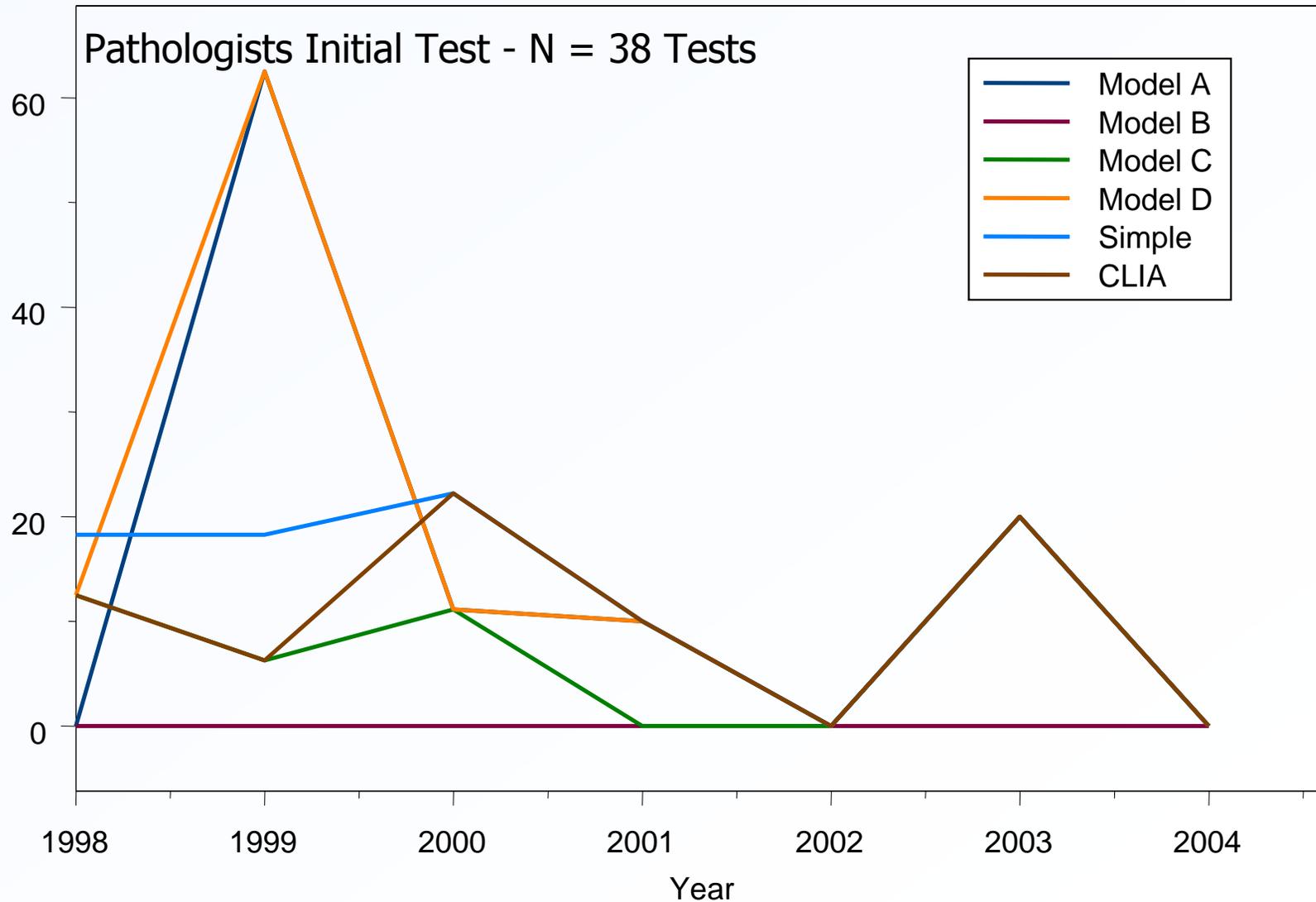
Grading Scheme Comparison

% Pathologists with Cytotechnologist scoring less than 90%
Initial test, 1998-2004; N=1272 tests

Grading Model	Range		Average
	Low	High	
Simple	1.1	5.1	3.0
CLIA	2.3	5.1	3.2
Model A	0.5	3.2	1.8
Model B	0.0	1.1	0.6
Model C	0.6	3.4	1.7
Model D	0.6	3.4	1.9



Grading Scheme Comparison: Percent Scoring <90%, MD Data 1998-2004





Grading Scheme Comparison: ASCP Data Analysis

2005, initial and first retest scores combined

Percent scoring less than 90%

	Grading Scheme				
	CLIA	A	B	C	D
Personnel					
CT N=6467	7.0	9.0	8.0	4.0	4.0
MD w/ CT N=5999	9.6	4.5	3.8	7.7	8.1
Solo MD N=650	26.9	15.1	13.5	21.7	23.2



Grading Scheme

MD Data Analysis/Summary

- Cytotechnologists: Results with
 - ❖ Model A and CLIA not significantly different from one another ($p=.84$)
 - ❖ Models B, C, and D are significantly different from CLIA ($p<.0001$ for all three)
 - ❖ Models B, C, and D not significantly different from each other (odds ratios have overlapping confidence intervals)
- Pathologists with cytotechnologists:
 - ❖ Results with all proposed models significantly different from CLIA (A, $p=0.02$; B, C, D, $p<0.0001$)
- Solo Pathologists – sample size too small
- Retest – sample size too small



Work Group Considerations

- Changes to point values had an impact on the % scoring <90%
- Changes should address significance of a miss; items identified as important include:
 - ❖ Unified or separate grading scheme for pathologists and cytotechnologists
 - ❖ Loss of points for pathologists not distinguishing LSIL/HSIL
 - ❖ Point value for correct response of negative when called unsatisfactory
 - ❖ Point value for correct response of LSIL when called unsatisfactory



Work Group Comment

- Unified or separate grading scheme for pathologists and cytotechnologists – differing opinions
- Loss of points for pathologists not distinguishing LSIL/HSIL – differing opinions
- Point value for correct response of negative when called unsatisfactory – 5 points for a 10 challenge test (current CLIA scheme)
- Point value for correct response of LSIL when called unsatisfactory – 0 points (currently 5 points)

New Models were created to reflect these decisions



Model E Grading Schemes

Point values in blue italics represent a change from CLIA scoring

Correct Response	Model E -10-Slide Test - Unified			
	Examinee Response			
	A – UNSAT	B-NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	0	0
B – NEGATIVE	5	10	0	0
C – LSIL	<i>0</i>	0	10	<i>10</i>
D – HSIL	0	<i>0</i>	<i>10</i>	10



Model F Grading Scheme

Point values in blue italics represent a change from CLIA scoring

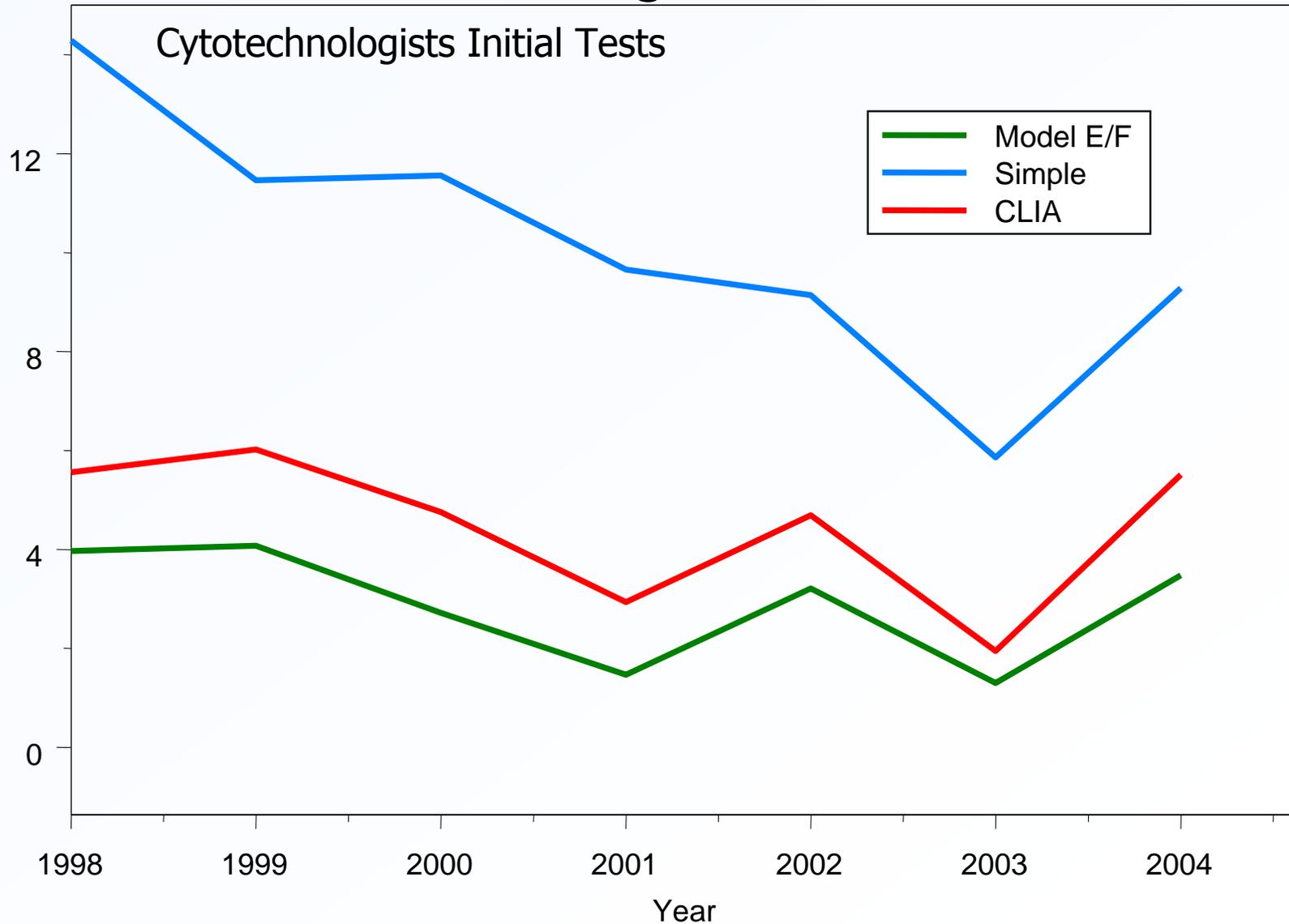
Correct Response	Pathologist (Technical Supervisor) 10-Slide Test			
	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	0	0
B – NEGATIVE	5	10	0	0
C – LSIL	<i>0</i>	0	10	<i>7.5</i>
D – HSIL	0	<i>0</i>	<i>7.5</i>	10

Correct Response	Cytotechnologist 10-Slide Test			
	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	10	0	<i>0</i>	<i>0</i>
B – NEGATIVE	5	10	<i>0</i>	<i>0</i>
C – LSIL	<i>0</i>	0	10	10
D – HSIL	0	<i>0</i>	10	10



Grading Scheme Comparison: New Workgroup Models E/F

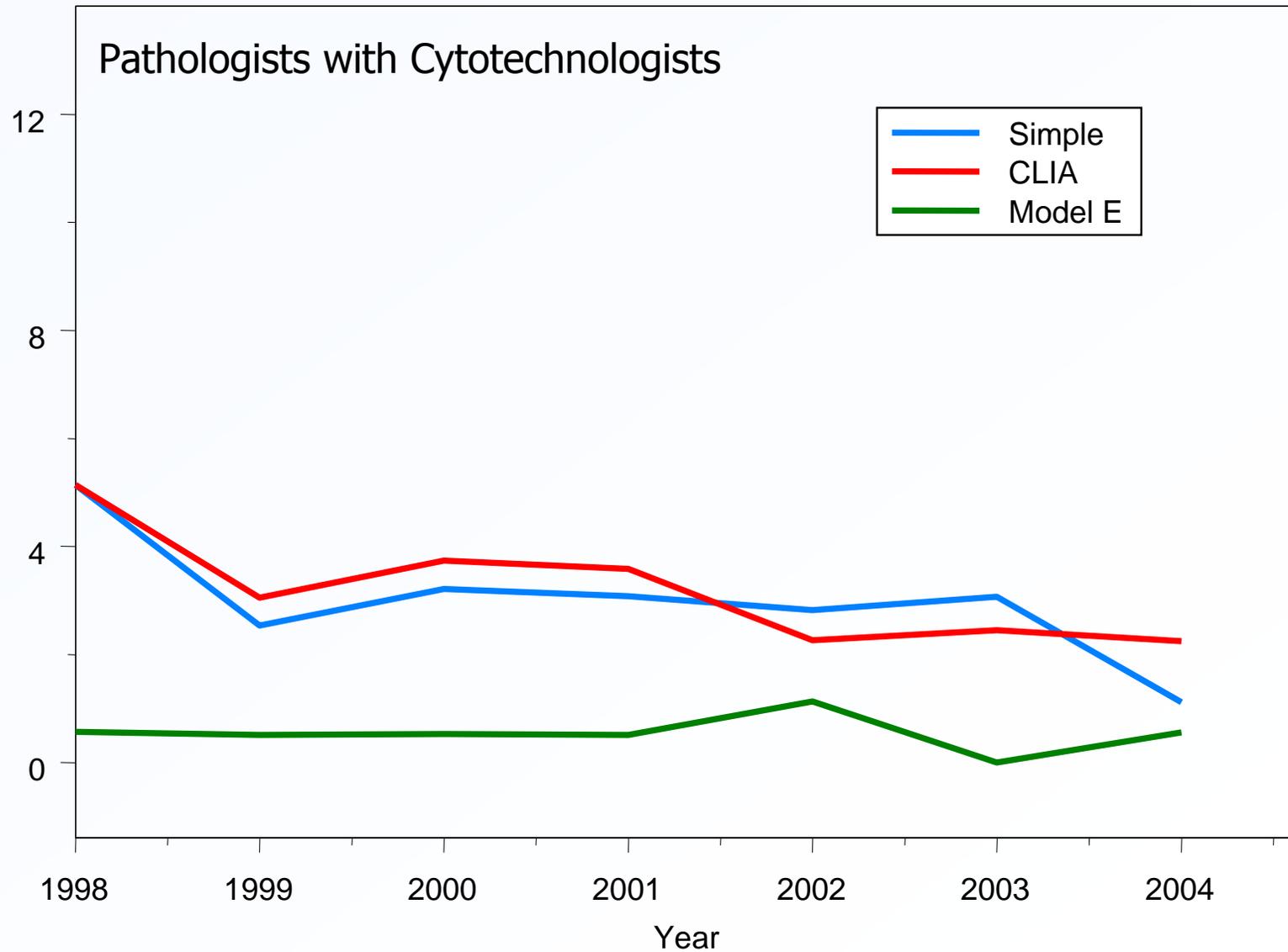
Percent Scoring <90%, MD Data 1998-2004





Grading Scheme Comparison: New Workgroup Model E

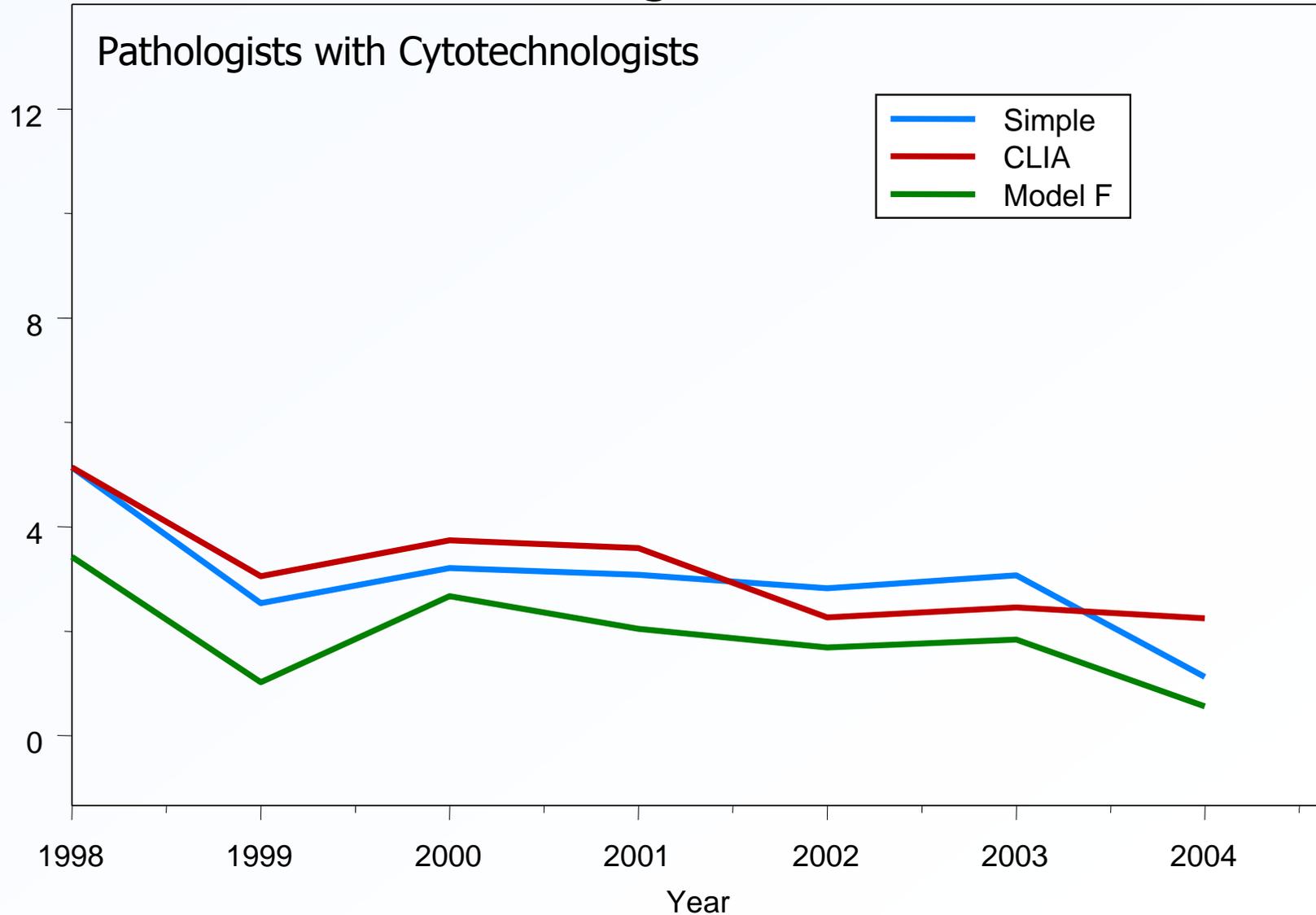
Percent Scoring <90%, MD Data 1998-2004





Grading Scheme Comparison: New Workgroup Model F

Percent Scoring <90%, MD Data 1998-2004





Number of Challenges Workgroup Comment

- 20 slides, challenges, or case equivalents over 2-year period with 4 hours to take the test



Number of Challenges

MD Data Evaluation

- 20-slide test simulation created by combining consecutive first 10-slide tests for the same individual over 2 years (1999-2000, 2001-2002, 2003-2004)
- 10-slide comparison created by averaging overall no-pass rate for two years (no change from current)



CLIA Grading Scheme

20 sides (Second and Third Retest)

Correct Response	Pathologist (Technical Supervisor) 20-Slide Test			
	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	5	0	0	0
B – NEGATIVE	2.5	5	0	0
C – LSIL	2.5	0	5	2.5
D – HSIL	0	-10	2.5	5

Correct Response	Cytotechnologist 20-Slide Test			
	Examinee Response			
	A – UNSAT	B- NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	5	0	2.5	2.5
B – NEGATIVE	2.5	5	2.5	2.5
C – LSIL	2.5	0	5	5
D – HSIL	0	-10	5	5



Number of Challenges: Analysis/Summary

% Cytotechnologists scoring less than 90%
Initial test, 1998-2004; N=2687 tests

Model	1999-2000		2001-2002		2003-2004	
	20*	10**	20*	10**	20*	10**
Simple	12.9	11.5	11.1	9.4	6.4	7.6
CLIA	6.9	5.4	4.9	3.9	5.2	3.7
Model A	5.0	5.1	4.4	3.7	1.5	3.2
Model B	3.1	3.3	1.4	1.7	1.1	2.4
Model C	1.4	2.4	0.3	0.9	0.8	1.5
Model D	1.4	2.6	0.3	1.2	0.8	1.5

* Rates created by combining 2 consecutive 10-slide tests for the same individual

** Rates created by averaging overall rate for 2 years



Number of Challenges: Analysis/Summary

% Pathologists with Cytotechnologist scoring less than 90%
Initial test, 1998-2004; N=1272 tests

Model	1999-2000		2001-2002		2003-2004	
	20*	10**	20*	10**	20*	10**
Simple	2.4	2.9	2.6	3.0	1.4	2.1
CLIA	2.4	3.4	1.3	2.9	2.7	2.4
Model A	1.2	1.9	1.9	1.9	0.7	1.5
Model B	0.0	0.5	0.7	0.8	0.0	0.3
Model C	0.0	1.3	0.0	1.9	0.0	1.2
Model D	0.6	1.8	0.0	1.9	0.0	1.2

* Rates created by combining 2 consecutive 10-slide tests for the same individual

** Rates created by averaging overall rate for 2 years



Number of Challenges Analysis Summary

- Simulation not comparable to a single 20-slide test
- Difficult to draw conclusions from this evaluation of rates for those not passing with the 20-slide simulation compared with the average for 10-slide tests
- For a true comparison, study needed to evaluate actual results from 10- and 20-slide tests



Frequency of Testing Workgroup Comments

- Less frequent testing of individuals
- Intervals suggested
 - ❖ 2 years
 - ❖ 3 years
 - ❖ >3 years



Frequency Comment

- MD data inadequate for evaluating testing frequency
 - ❖ Annual testing experience confounds evaluation
 - ❖ Probability of scoring $\geq 90\%$ on 1st test = 91%
 - ❖ Probability of scoring $\geq 90\%$ = 97% after 1st test
- NY converted from annual testing to every 2 years:
 - ❖ Change made for pragmatic reasons
 - ❖ Retrospectively did not have a change in failure rates



Summary

Items for Discussion

- Grading scheme
 - ❖ Model E
 - ❖ Model F
- Number of challenges
 - ❖ 20 challenges
 - ❖ 10 challenges for initial test and first retest; 20 challenges for second and third retest (currently in CLIA)
- Frequency of testing
 - ❖ 2 years
 - ❖ 3 years
 - ❖ >3 years



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