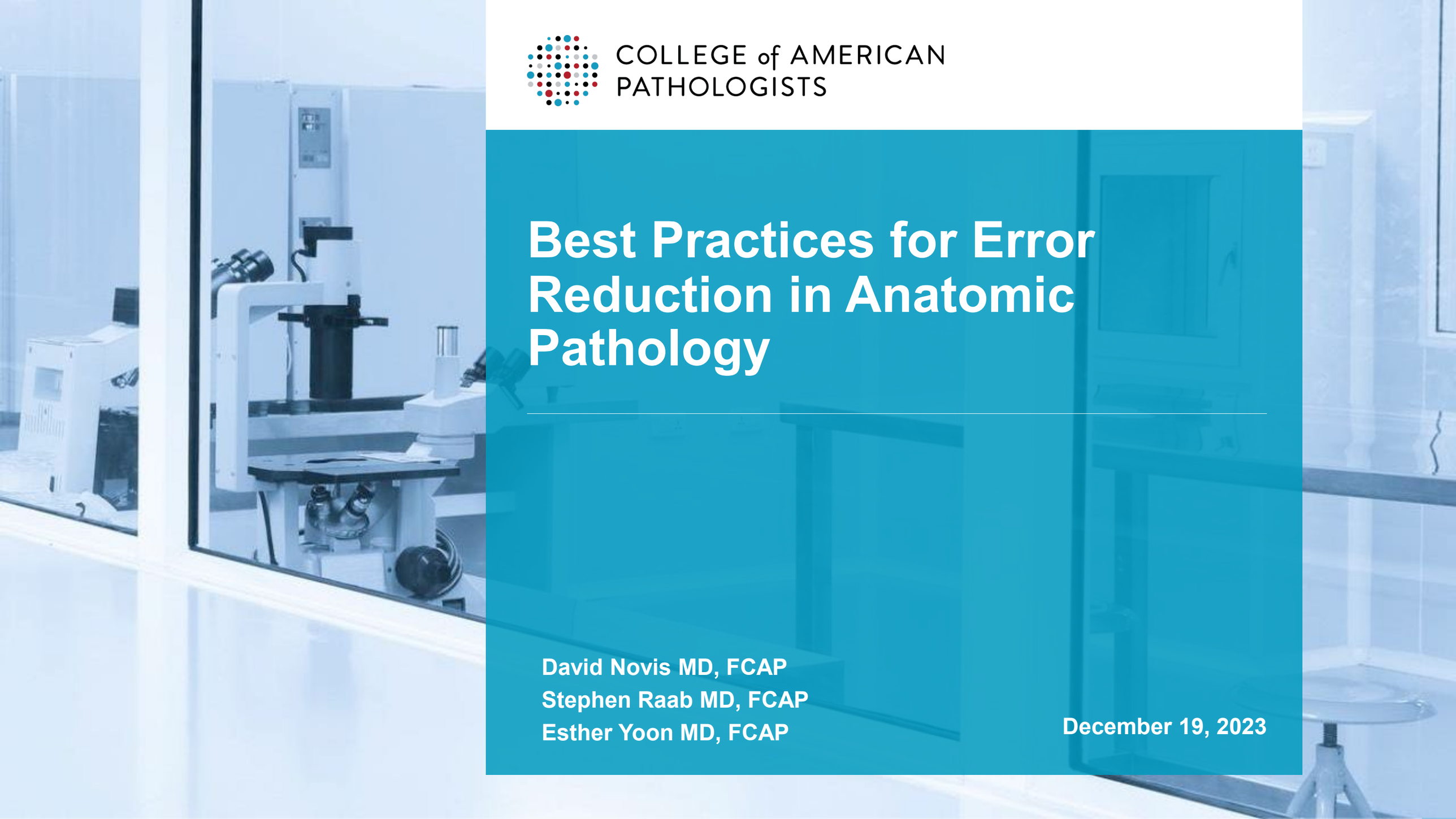

COLLEGE of AMERICAN PATHOLOGISTS

Best Practices for Error Reduction in Anatomic Pathology

David Novis MD, FCAP
Stephen Raab MD, FCAP
Esther Yoon MD, FCAP

December 19, 2023

David Novis, MD FCAP

- Owner, CEO Novis Consulting LLC.
- Managing Partner (Ret., Young Novis PA
- Entrepreneur, Business Developer
- Lean Certification, University of Pittsburgh and Henry Ford Hospital
- Past CAP Positions:
  - Speaker of the House of Delegates
  - Member of CAP Board of Governors
  - Vice Chair Quality Practice Committee

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Stephen Raab, MD CAP

- AP/CP Pathologist >30 years
- Medical Officer Agency for HealthCare Research and Quality
- Co-Chair, CAP Interpretive Diagnostic Error Committee.
- Researcher, educator, author in quality and error reduction.
- Recipient CAP Humanitarian Award and Lansky Award (leadership)

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Esther Yoon, M.D., FCAP

- Section Head in Surgical Pathology, Florida Region, Cleveland Clinic
- New In Practice Committee, CAP
- Member - CAP, USCAP, ASCP
- Board certified AP/CP
- Fellowships: Breast & GYN (2018) and Cytopathology (2019)

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Disclaimer

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This should not be used as a substitute for professional assistance.

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Errors in Anatomic Pathology
The Current State

Esther Yoon, M.D. FCAP

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Errors = Amendments ?

- How are we doing now?
- Effect of practice setting on error
- Effect of case volume on error
- Can we do better than counting amendments?

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CAP TODAY

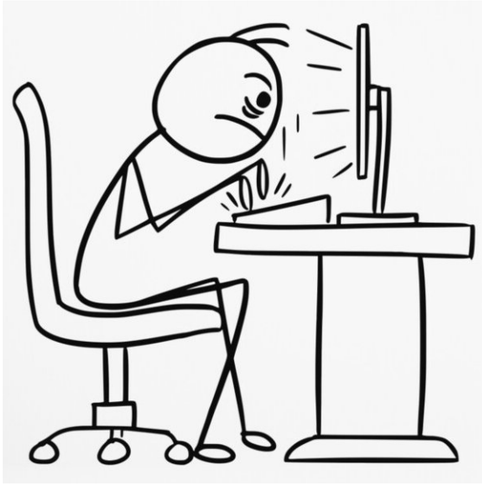
Pathology • Laboratory Medicine • Laboratory Management

Q&A column

in 2022 Issues, August 2022, In Every Issue, Q&A column

Q. Every month our anatomic pathology laboratory amends patient reports. Does the CAP have a benchmark for amended reports, such as how many are acceptable per month?

- **Amendment rates range from 0.1 to 10 percent**
  - **does not provide a benchmark for amended reports.**



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Pathology Report and Errors

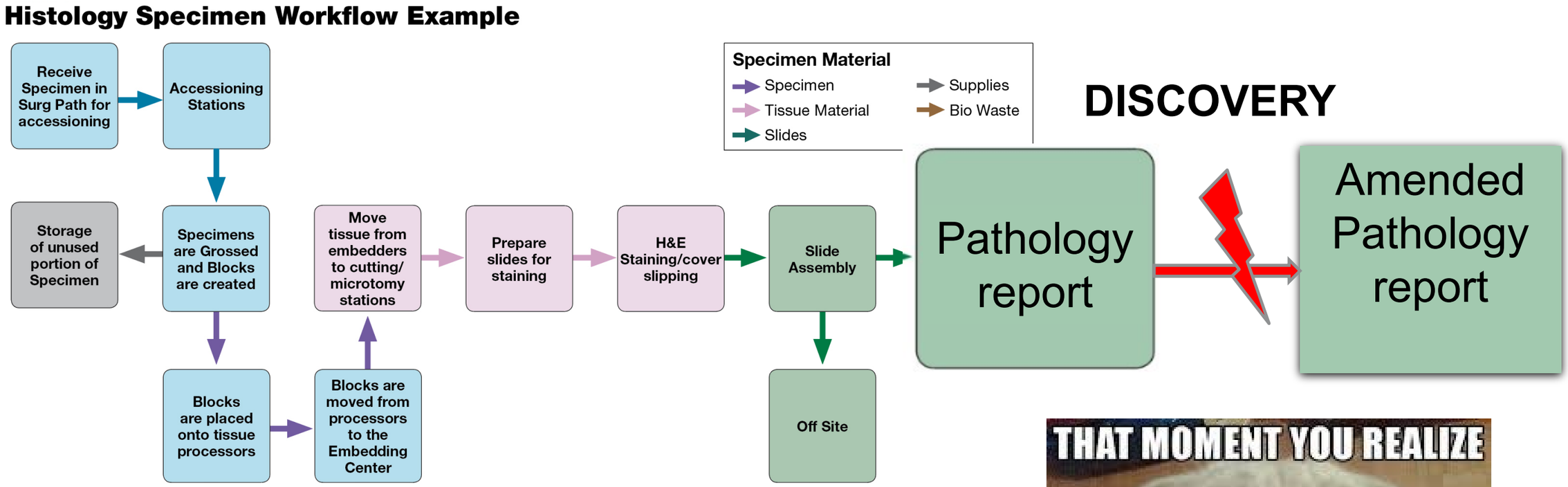

Image modified from https://www.medlabmag.com/article/1436

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Surgical pathology report defects: a College of American Pathologists Q-Probes study of 73 institutions.

- 73 participating institutions
- Median defect rate of 5.7/1000 reports

DEFECT (ERROR) RATES	
HIGHER	LOWER
Training program	Pre- and Post- sign out Review

Volmar KE, et al. Surgical pathology report defects: a College of American Pathologists Q-Probes study of 73 institutions. Arch Pathol Lab Med. 2014 May;138(5):602-12.

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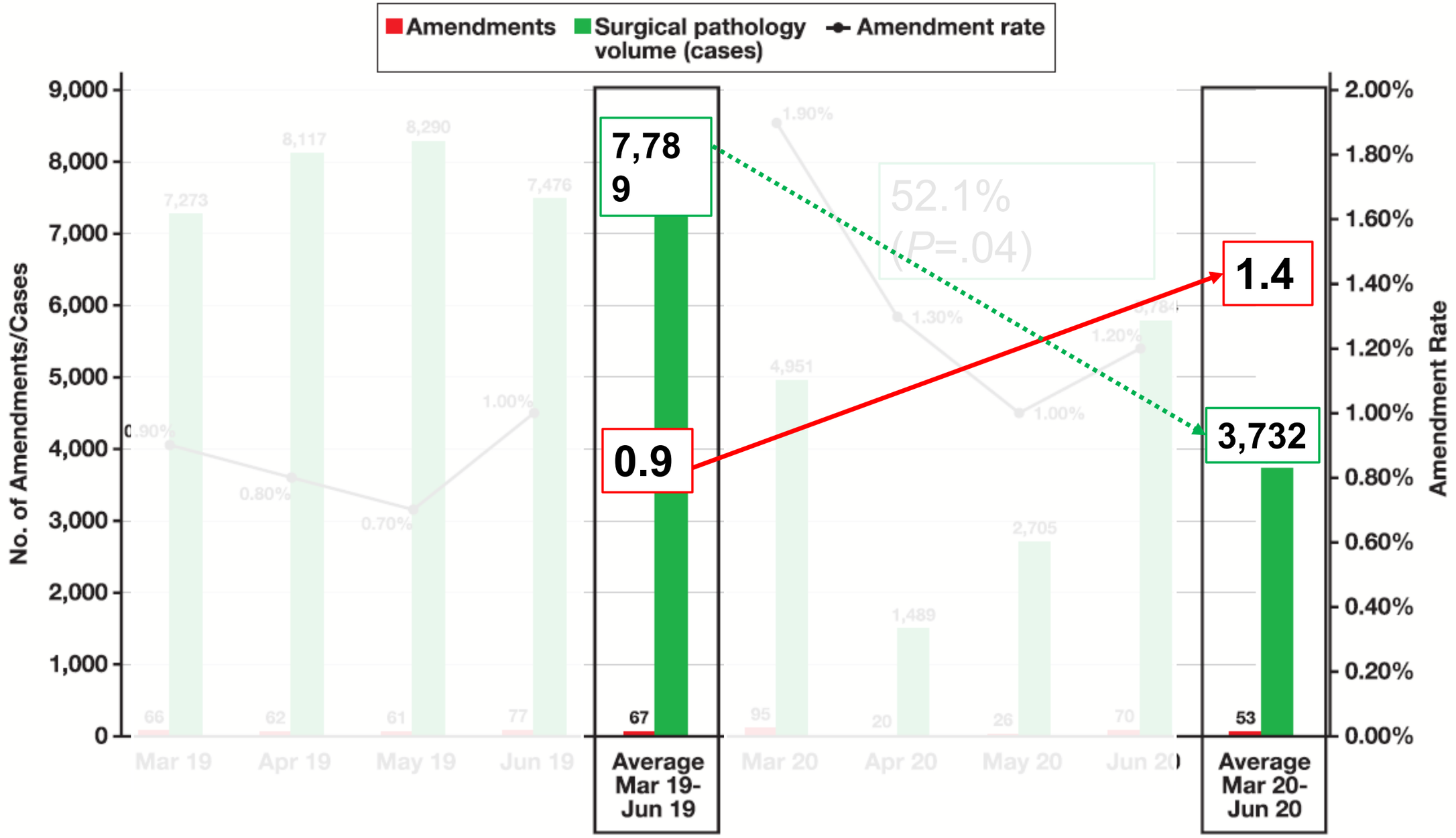

FIGURE 1 Number of amendments and case volume each month (y-axis, left). Rate of amendments each month (y-axis, right).

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Harris CK, et al. Changes in Surgical Pathology Case Volume and Amendment Rates During the COVID-19 Pandemic. Am J Clin Pathol. 2022 Jul 1;158(1):142-147.

% Change in amendments

Types of "Amendments"	Identification (%)	Report defect (%)	Diagnostic information (%)
Total change (*P*=.46)	-53.3	-3.8	23.2

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Tracking Errors

- Amended Reports
  - Underestimation of magnitude: Follow up
  - Underestimation of severity: Who Decides?
  - Retrospective: Too little too late

- Revised Reports:
  - Accurate estimate
  - Prospective: mitigates risk
  - Promotes intradepartmental standardization

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Reducing AP Errors
What Works?

Stephen Raab, M.D.

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Why Do a Secondary Review

1. Types and methods of secondary review
2. The benefits of disagreement
3. Standardization of reports

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What does a blinded retrospective secondary review of a cohort of surgical pathology and cytopathology specimens show?

The College of American Pathologists and the Association of Directors of Anatomic and Surgical Pathology expert panel (2015)

Evidence-based guidelines

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What does a blinded retrospective secondary review of a cohort of specimens show?

Guideline Statement 1 – Summary of Studies

Discrepancy rates (%)		Major Discrepancy rates (%)	
No. of studies	Median (25^{th}-75^{th} percentile)	No. of studies	Median (25^{th} – 75^{th} percentile)
116	18.3 (7.5-34.5)	78	5.9 (2.1-10.5)

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Science Behind Discrepancies—Sources of Variations

1. Processes occurring in the patient
2. Diagnostic pathways
3. Pathologist observers

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Science Behind Discrepancies– Pathologist Judgements of Diagnoses

Imprecise judgment
(noise or repeatability)

↓

You are uncertain this tumor is A or B, but do not consider the possibility of C

We don't know what we don't know

Inaccurate judgment
(absence of truth or bias)

↓

You are confidant that this tumor is reactive for S100, when it is not

Best Detected and Resolved By…

↓

Case Review

↓

Standardization

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Agreement for Juror First Votes

Table 1: Demographics and Juror First Vote

	Not Guilty	*Undecided*	*Guilty*	*n*	*p-Value*
African-American juror	46%	13%	41%	743	0.000***
White juror	31%	12%	57%	1,298	0.000***
Hispanic juror	36%	15%	49%	629	0.542
African-American juror-minority defendant	47%	12%	40%	651	0.000***
African-American juror-white defendant	22%	11%	67%	18	0.140
White juror-minority defendant	32%	13%	55%	960	0.008***
White juror-white defendant	30%	10%	60%	136	0.312
Hispanic juror-minority defendant	36%	13%	51%	496	0.955
Hispanic juror-white defendant	33%	9%	58%	33	0.617
Male	36%	11%	53%	1,206	0.311
Female	36%	15%	50%	1,920	0.311

NOTE: Significance levels test the hypothesis that the variables listed in the first column are not associated with a juror's first vote. Significance levels were calculated using ordered logit regression models accounting for the nonindependence of jurors who sat on the same case. The juror's first vote served as the dependent variable. Dummy variables reflecting the juror characteristic or juror characteristic-defendant characteristic combination listed in the first column served as the independent variable.

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Interpretive Summary of Guideline Recommendations

- Implement procedures to **detect disagreements and interpretive errors.**
- **Perform case reviews** in manners timely enough to improve patient care.
- **Document case reviews** and case review procedures.
- **Track outcomes** of case reviews.
- Implement procedures to **maximize diagnostic agreement**.

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Retrospective vs Prospective Review

Retrospective	Prospective
Fixed baseline error rate	Dynamic evolving error rate
Delayed error correction	Immediate error correction
Individual or team activity	Team activity

Nair R, Aggarwal R, Khanna D. Methods of formal consensus in classification/diagnostic criteria and guideline development. Semin Arthritis Rheum. 2011 October ; 41(2):95–10 doi:10.1016/j.semarthrit.2010.12.001.

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Models of Retrospective Case Review

- Formal Model*
- Difficult case conference review,
- Curbside consults
- Secondary opinion (pre-sign-out)
- Tumor boards
- Send outs
- Others.

Nair R, Aggarwal R, Khanna D. Methods of formal consensus in classification/diagnostic criteria and guideline development. Semin Arthritis Rheum. 2011 October ; 41(2):95–10 doi:10.1016/j.semarthrit.2010.12.001

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Methods of Prospective Case Review

- Rapid pre-review (e.g., hot seat review)
- Reference class forecasting
- Dyad or team sign-out
- Pilot-Co-pilot diagnosis
- Calibration exercises

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Team Signout in a Private Pathology Practice 12K-Accessions

David Novis, MD FCAP

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Objectives

- Review Protocol
- Requirements
- Standardization
- Outcomes
- Considerations

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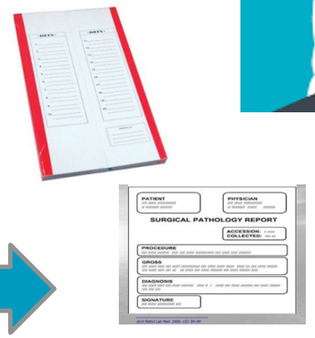
Team Protocol

1

1



2

2

Reports Signed by Both Pathologists

3

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Case Review Protocol

- 100% Prospective Review

- *Quality Control*—NOT a double blind read

  - Is what's on the report on the slides?
  - Is what's on the slides in the report?
  - Is the report readable and grammatically correct?
  - Does the report address the clinical question?

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Requirements of 100% Prospective Review

Culture

- Intolerance of defects
- Tolerance of work styles
- Group rather than individual accountability
- Trust

Standardized criteria (templates)

- ALL diagnoses
- Diagnostic terms

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Standardized Reporting Templates
Diagnostic Terms and Criteria

**GRADING OF BREAST DUCTAL ADENOCARINOMA
(Nottingham modification of Bloom & Richardson criteria)[a]

SCORE	TUBULE LUMENS	CYTOLOGY	MITOSES/10 HPF(40X):
1	>75% clear	small, uniform	<0-5
2	10-75% clear	some nucleoli	6-10
3	≤10% lumens	anaplastic[b]	>10
TOTAL:	(3-5) GRADE I	(6-7) GRADE II	(8-9) GRADE III

[a] Elston CW, Ellis IO. Pathological prognostic factors in breast cancer. I. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 19:403-410, 1991.
[b] anaplastic: >25% of nuclear diameters > 2rbc; nuclear shape variable; >25% of nuclei possess nucleoli, nuclear chromatic coarse, clumped

GRADING OF DUCTAL CARCINOMA IN SITU OF THE BREAST*

SCORE	Nuclear Size	Nuclear Chromatin	Nucleoli
1	1-1.5 rbc	diffuse	none
2	1.5-2 rbc	coarse	rare
3	>2 rbc	vesicular	many
TOTAL:	(3-5) GRADE I	(6-7) GRADE II	(8-9) GRADE III

* Taken from: Schnittt SJ, Harris JR, Smith BL. Developing a prognostic index for ductal carcinoma in situ of the breast. *Cancer* 1996; 77:2189-2274

GRADING OF ENDOMETRIAL ADENOCARCINOMA[1]

ARCHITECTURAL GRADE

Architectural Growth Pattern (% Solid Growth)	FIGO Glandular Nuclear Atypia[2] Absent	FIGO Glandular Nuclear Atypia[2] Present	AJCC Glandular Nuclear Atypia[2] Absent	AJCC Glandular Nuclear Atypia[2] Present
5%	G1	G2	G1	G2
6-50%	G2	G3	G2	G3
>50%	G3	G3	G3	G4

[1] Minimal criteria for adenocarcinoma: cribriform, papillary glandular architecture or irregular glandular infiltration associated with desmoplastic stromal response involving at least 2.0 mm (1/4 of one 4x field)
[2] Glandular nuclear atypia: three of four following features-(1) pleomorphic, enlarged (2) coarse chromatin, vesicular (3) prominent nucleoli (4 mitoses>20/10hpf.
NOTE: The grade of the tumor from biopsy specimens agrees with the tumor grade in the hysterectomy specimens in less than 60% of the cases .
REFERENCE: modified from: Mazur M and Kurman RJ. Endometrial Carcinoma, *Diagnosis of Endometrial Biopsies and Curettings* (New York:Springer-Verlag, 1995),pp.184-218

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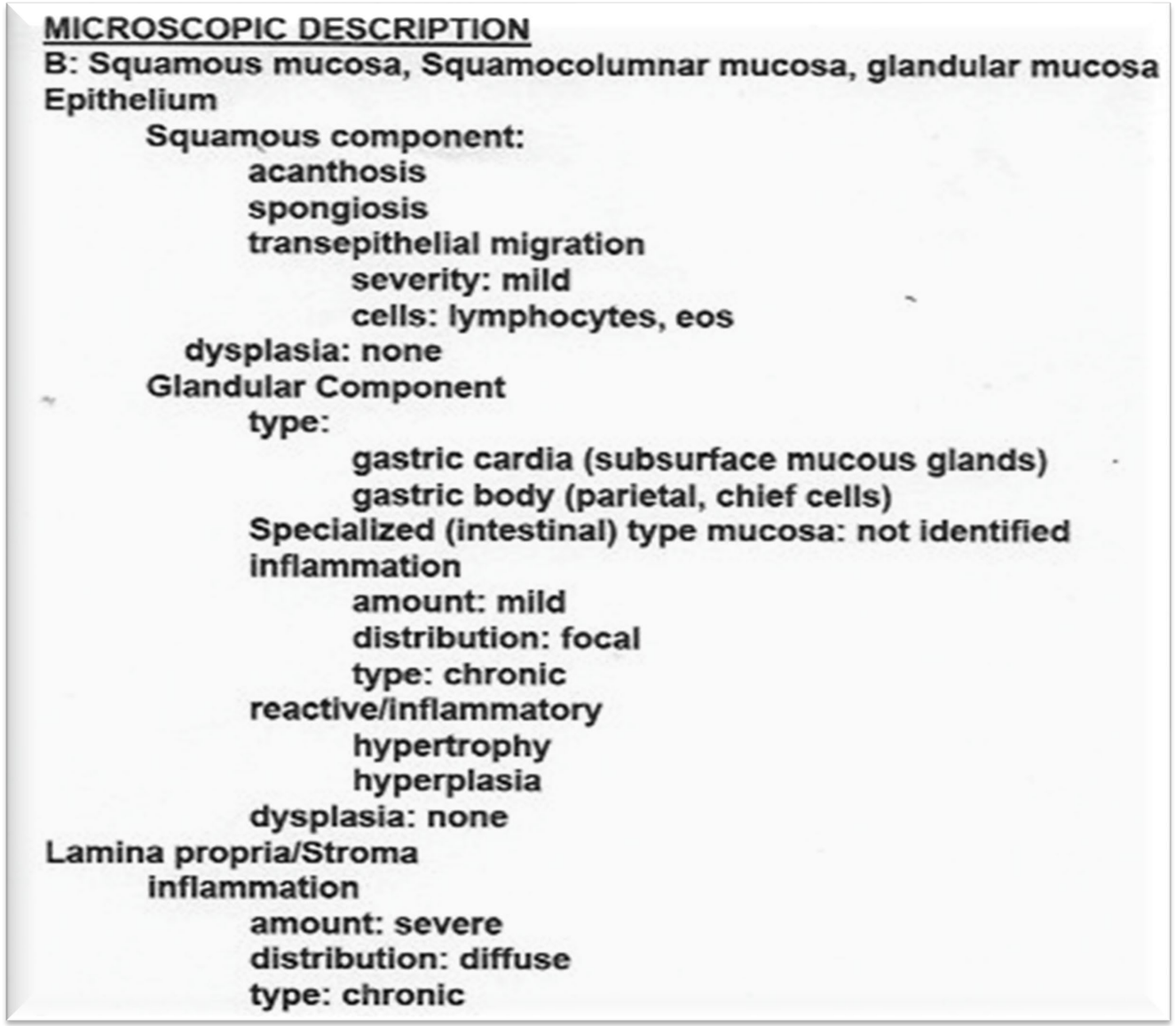
Standardized Reporting Templates



MICROSCOPIC DESCRIPTION
B: Squamous mucosa, Squamocolumnar mucosa, glandular mucosa
Epithelium
- Squamous component:
  - acanthosis
  - spongiosis
  - transepithelial migration
    - severity: mild
    - cells: lymphocytes, eos
  - dysplasia: none
- Glandular Component
  - type:
    - gastric cardia (subsurface mucous glands)
    - gastric body (parietal, chief cells)
  - Specialized (intestinal) type mucosa: not identified
  - inflammation
    - amount: mild
    - distribution: focal
    - type: chronic
  - reactive/inflammatory
    - hypertrophy
    - hyperplasia
  - dysplasia: none

Lamina propria/Stroma
- inflammation
  - amount: severe
  - distribution: diffuse
  - type: chronic

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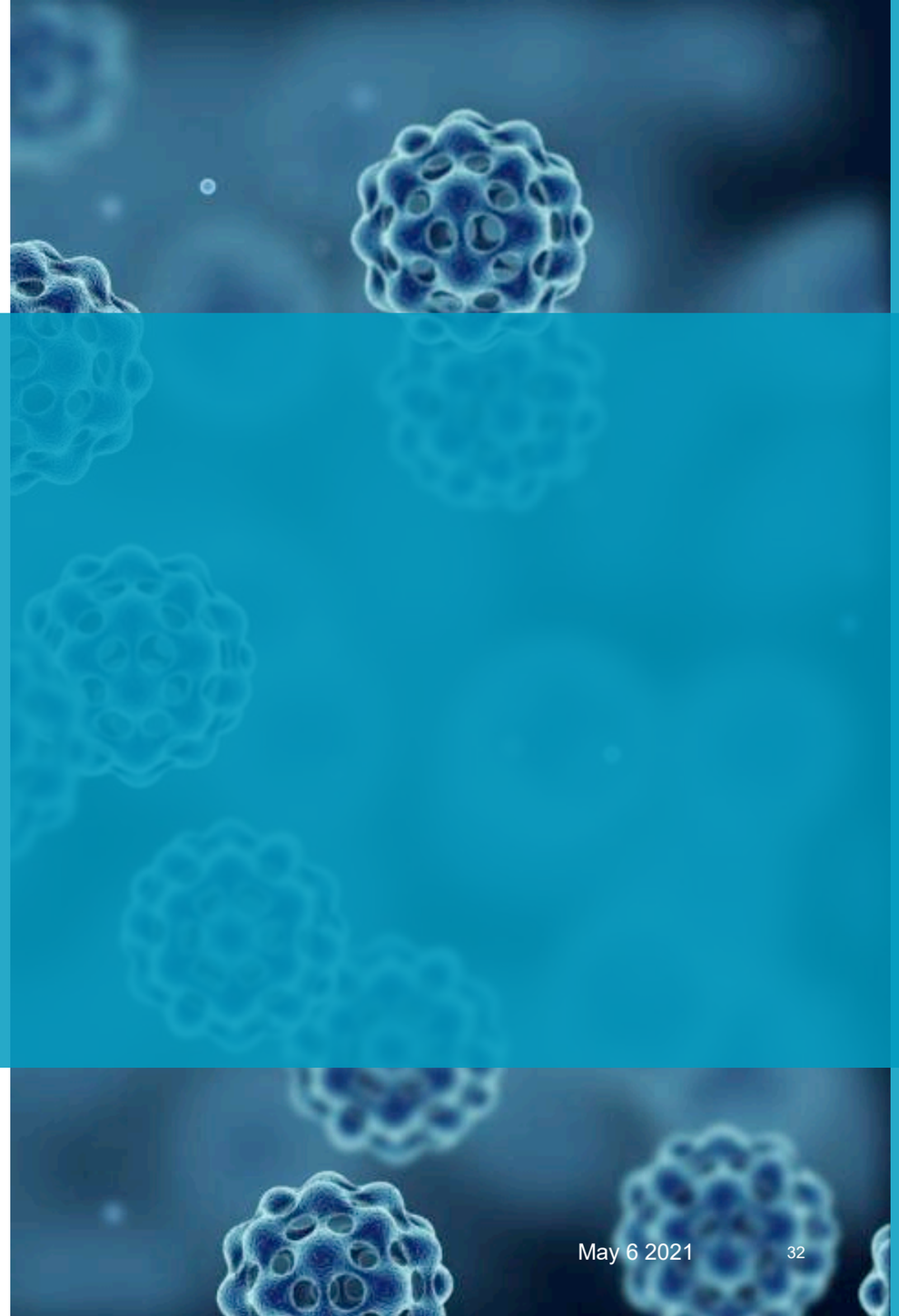
Outcomes

- Reduced errors
- Saved time
- Grew customer satisfaction
- Grew business



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Reduced Errors

- Amended Reports Rate Decreased From 6 to 1.2 per 10,000*
- Pre-release corrections—Revised Reports: 1/20-1/50

*https://davidnovis.com/wp-content/uploads/2014/03/Doubleread-copy-2.pdf

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Saved Time

1. Pareto
2. Standardized templates
   - Delegation (conversation not dictation)
   - Clicking on checklist items
3. Eliminate disruptive calls for 2nd looks

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Customer Satisfaction
Business Growth

- Review by second pathologist
- Templates
  - Customized
  - Complete
  - Customer input…Sense of ownership

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Provider Concerns

1. Delays turnaround time
2. Not paid for QC
3. Most errors do not affect patient care
    - Who decides that?
    - Coexisting conditions
    - How long is the follow up?
    - Nightmares

Bottom Line: Comfort level in releasing a defective report with your name on it

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QUESTIONS

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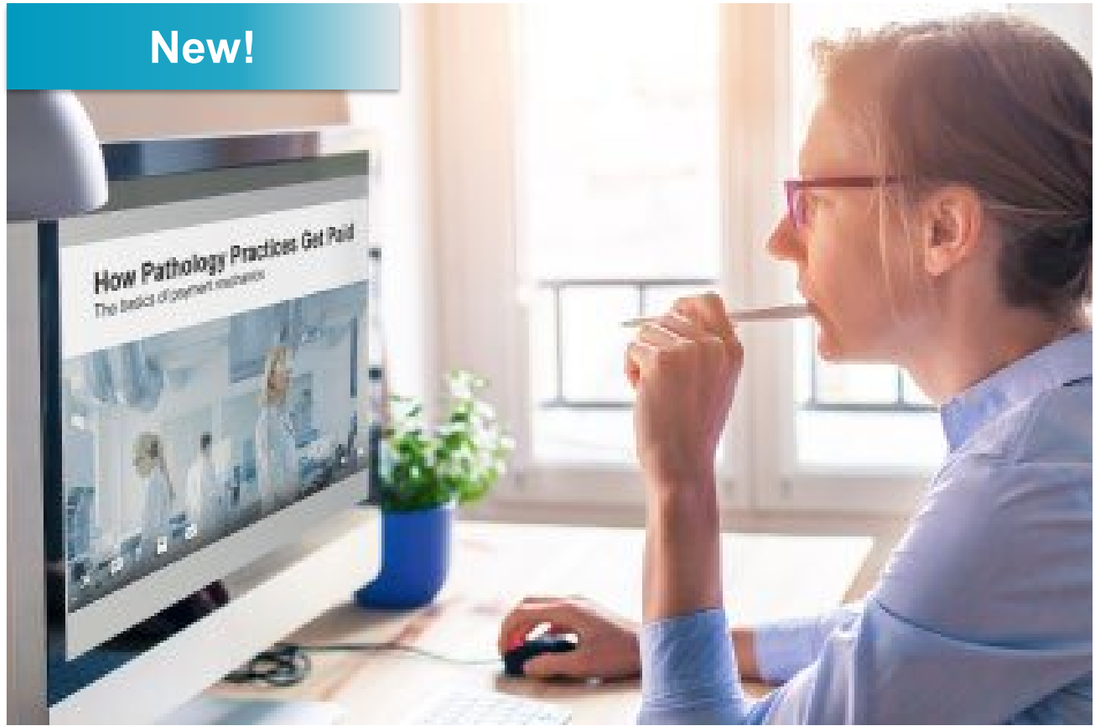
Pathology Business Fundamentals

Essential online courses to help grow your management skills to lead your practice



1. Relative Value Units (RVU's)—Understanding the Basics
2. How Pathology Practices Get Paid
3. Revenue Cycle Management
4. Analysis and Interpretation of Billing Reports
5. Basic Practice Cost Analysis
6. Capacity Management and Workflow Analysis
7. Basic Contracting and Fee Analysis
8. Basic Budget Development

Learn more
and register

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Additional Resources

Practice Management

- https://www.cap.org/member-resources/practice-management

Practice Management Articles

- https://www.cap.org/member-resources/articles/category/practice-management

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We value your feedback!

If after attending this discussion and later you applied any of what you learned to your practice, please share your feedback of how it worked for your practice at https://www.cap.org/member-resources/practice-management/practice-management-inquiry-form .

Watch for the session evaluation form. Your feedback is important!

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