CMPA

“Medical-legal Issues in Pathology”

Kathryn Reducka MD, Physician Risk Manager, CMPA

Pathology Update 2015

Toronto, ON November 14, 2015

Faculty / Presenter Disclosure

Faculty: Dr Kathryn Reducka

Employee of: CMPA

Relationships with commercial interests:

- Grants / Research Support: None
- Speakers Bureau / Honoraria: None
- Consulting Fees: None
- Other: None

Conflict of Interest - I have no financial or professional affiliation with any organization that can be perceived as a conflict of interest in the context of this presentation.

Information is for general educational purposes only and is not intended to provide specific professional medical or legal advice or constitute a "standard of care".

Objectives

- Identify three areas of medical-legal risk for pathologists
- Incorporate two strategies to reduce risk in your lab/practice

2 Women Have Endometrial Biopsy By GYN On Same Day

What slides did you report on ?

A Case of Mistaken Identity

Following the Investigation

- Created embedding log at time of gross pathology
- Forceps to be washed between specimens

CMPA

Professional Liability for Pathologists

2010 - 2014

 cmpa-acpm.ca

Question #1

- What is the most common critical incident in closed legal actions involving pathologist ?

A. Communication Issues
B. Delay/ Missed Diagnosis
C. Administrative issues
D. Performance issues

Question #1

- What is the most common critical incident in closed legal actions involving pathologist ?

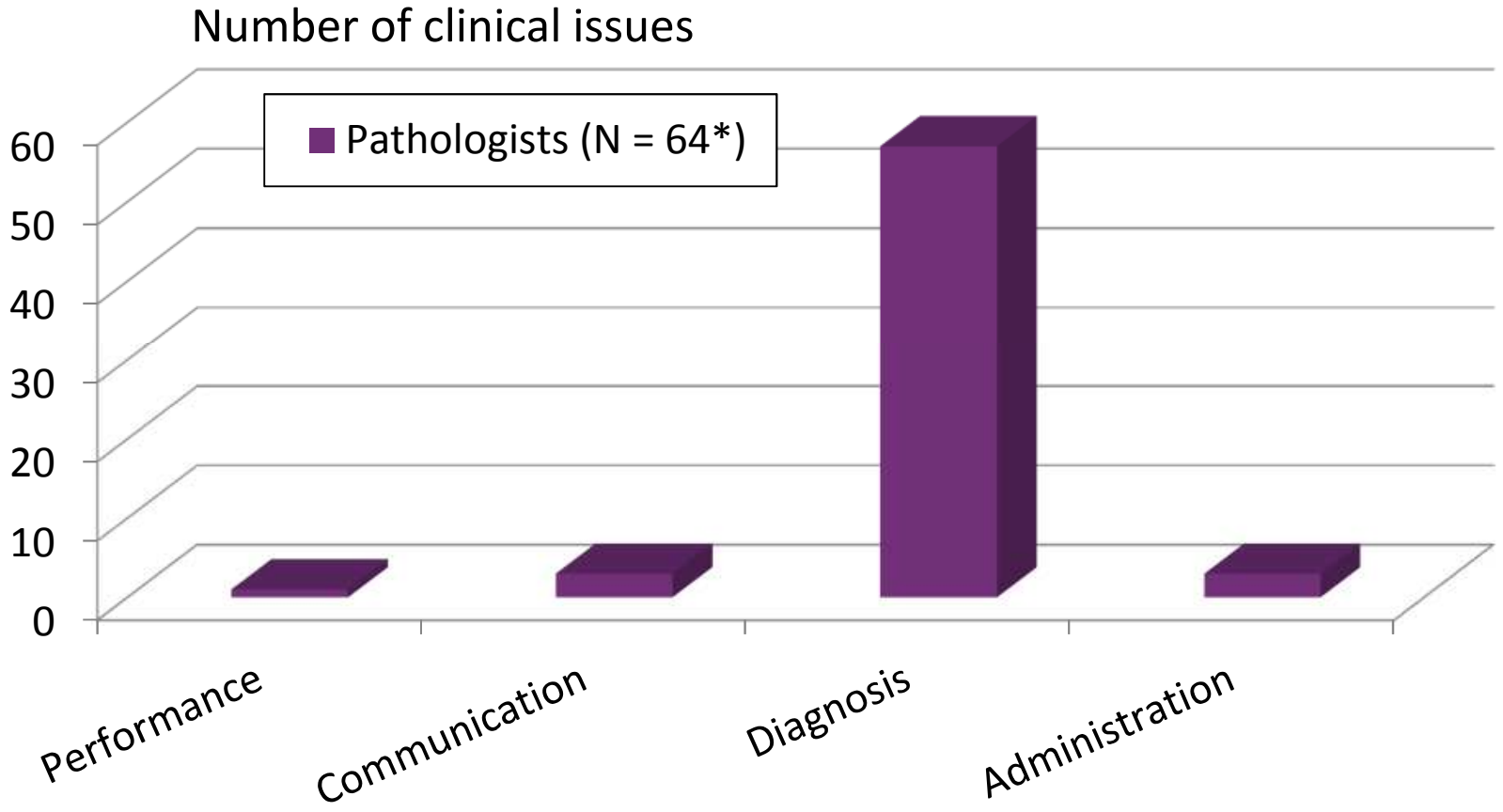
A. Communication Issues

B. Delay/ Missed Diagnosis

C. Administrative issues

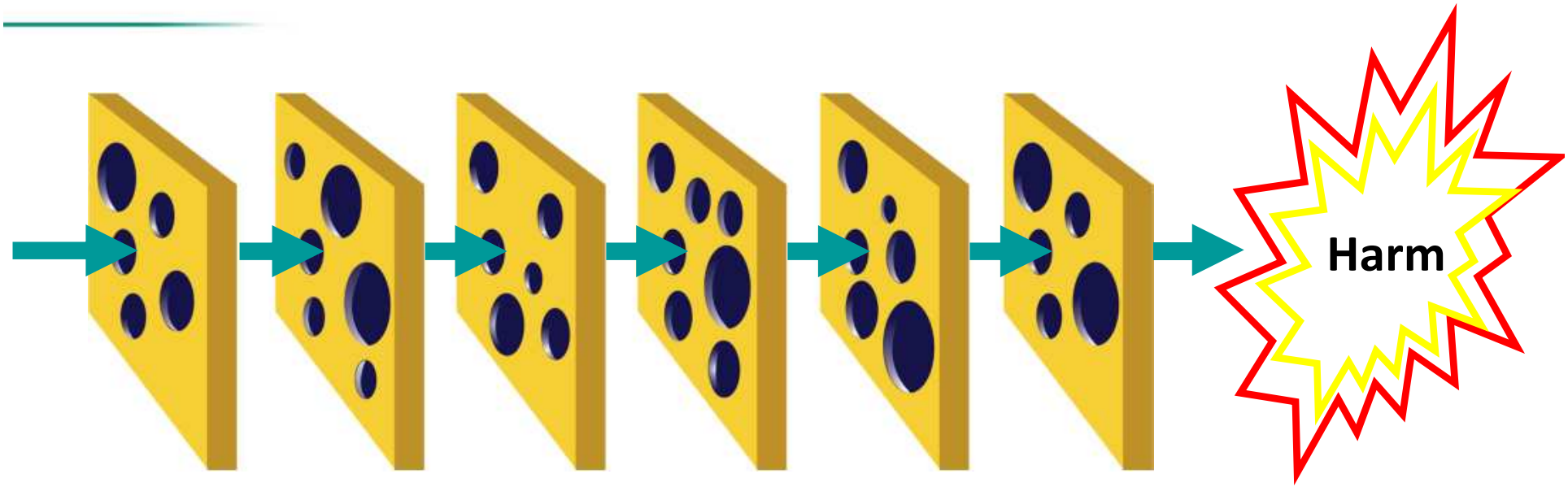
D. Performance issues

Clinical Issue
Legal Actions Closed 2010 - 2014



* Number of clinical issues

System Failure(s)



Funding & Resources

Organization
Culture

Incomplete policies

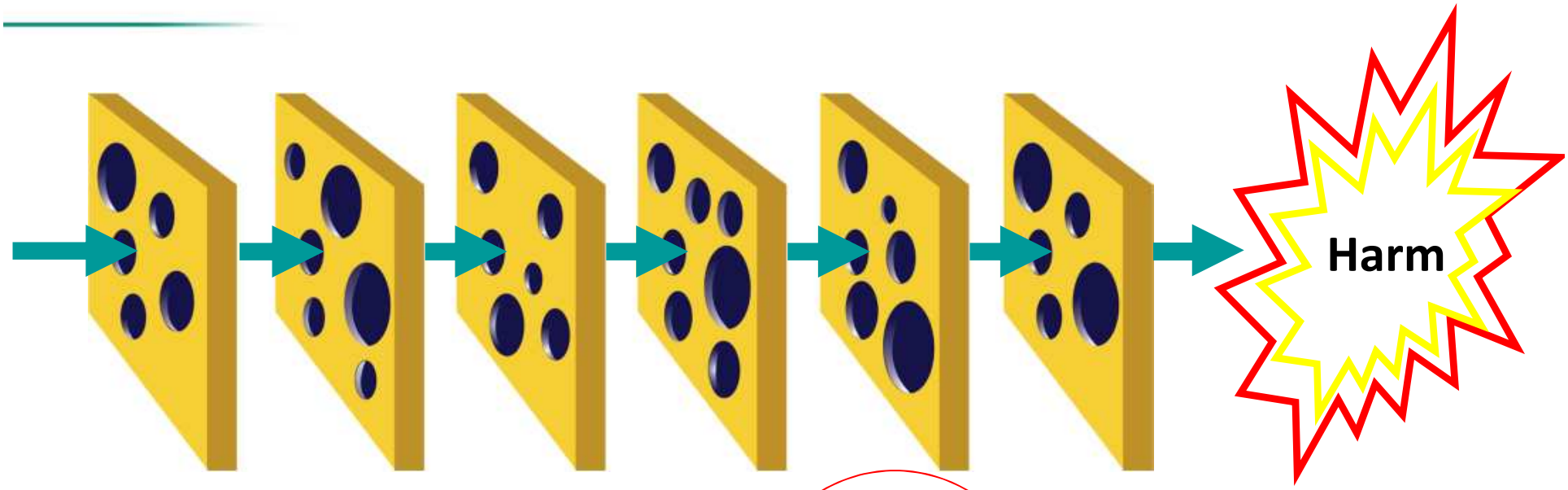
Pre-Analytic
Poor sampling
Inadequate history
Lost specimen

Analytic
Specimen Processing
Cognitive dispositions

Post-analytic
Disseminate reports
Clinician interprets
Clinician acts

From J. Reason

System Failure(s)



Funding & Resources

Organization
Culture

Incomplete policies

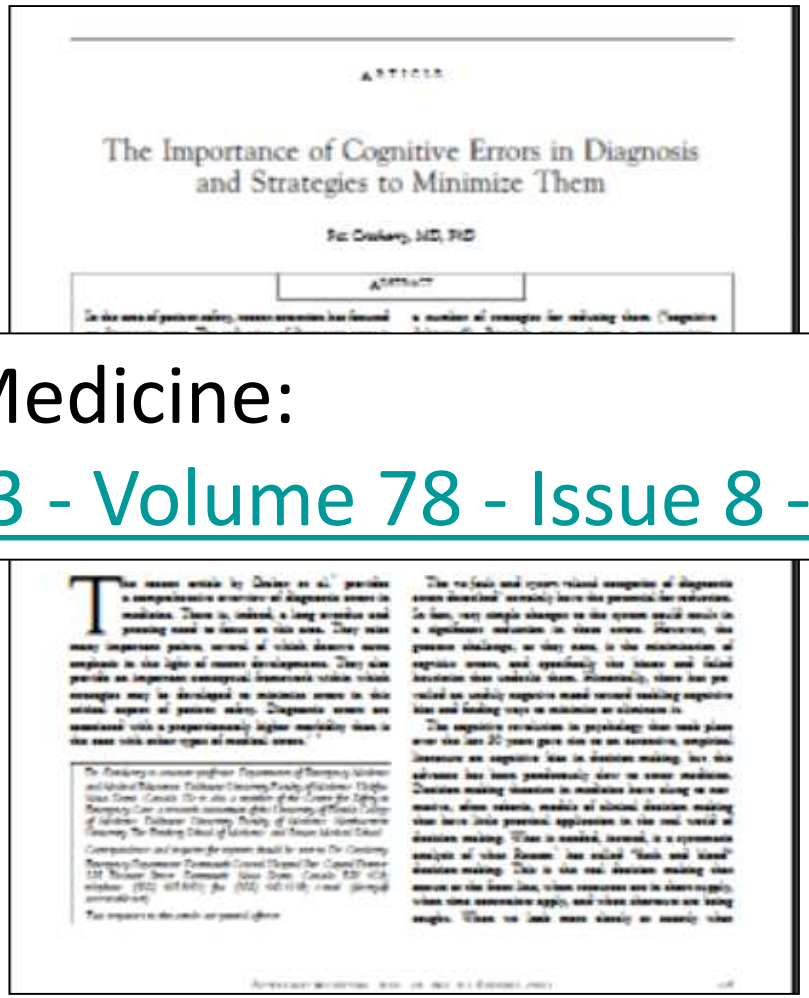
Pre-Analytic
Poor sampling
Inadequate history
Lost specimen

Analytic
Specimen
Processing
Cognitive dispositions
70%

Post-analytic
Disseminate reports
Clinician interprets
Clinician acts

From J. Reason

Cognitive forcing



The Importance of Cognitive Errors in Diagnosis and Strategies to Minimize Them

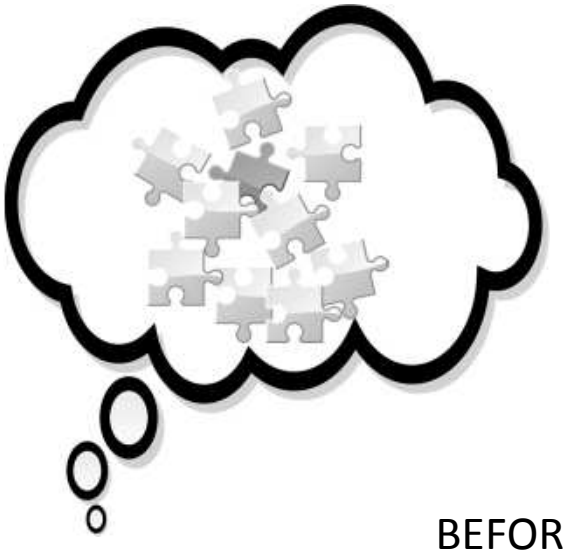
Academic Medicine:

August 2003 - Volume 78 - Issue 8 - p 775–780

Where is the abnormality?

Where is the abnormality?

Hindsight and Hindsight Bias

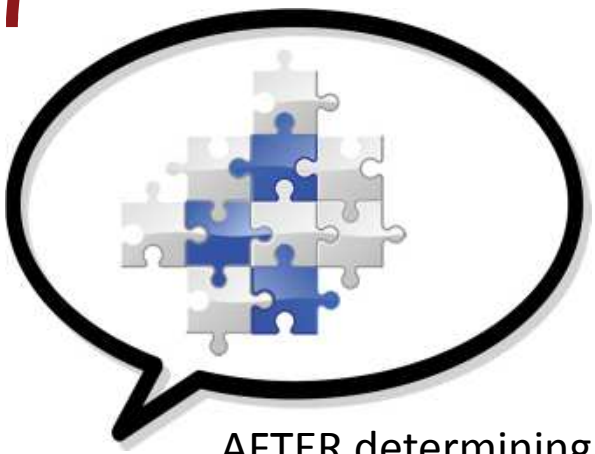


BEFORE arriving
at a final diagnosis

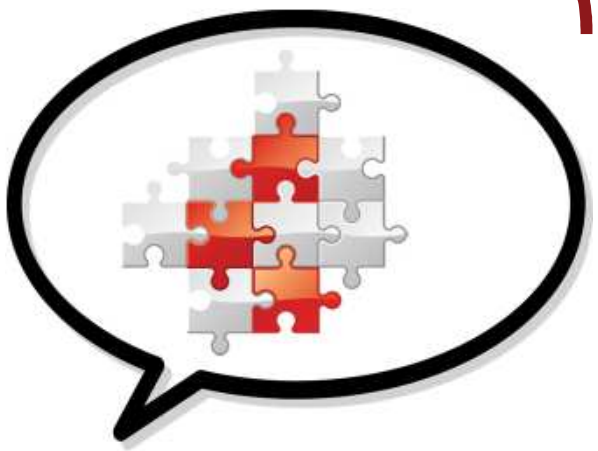
Hindsight and Hindsight Bias

The puzzle is solved, the final diagnosis is clear

BEFORE arriving at a final diagnosis



AFTER determining the final diagnosis



AFTER a delay in making a diagnosis or a misdiagnosis

What Can Lead to Misdiagnosis?

Question #2

- From CMPA cases what is the top reason for error in diagnosis for pathologists?

A. Lab mix-up
B. Failure to consult
C. Misreading/ misinterpretation of specimen
D. Not following protocols/ policies

Question #2

- From CMPA cases what is the top reason for error in diagnosis for pathologists?

A. Lab mix-up

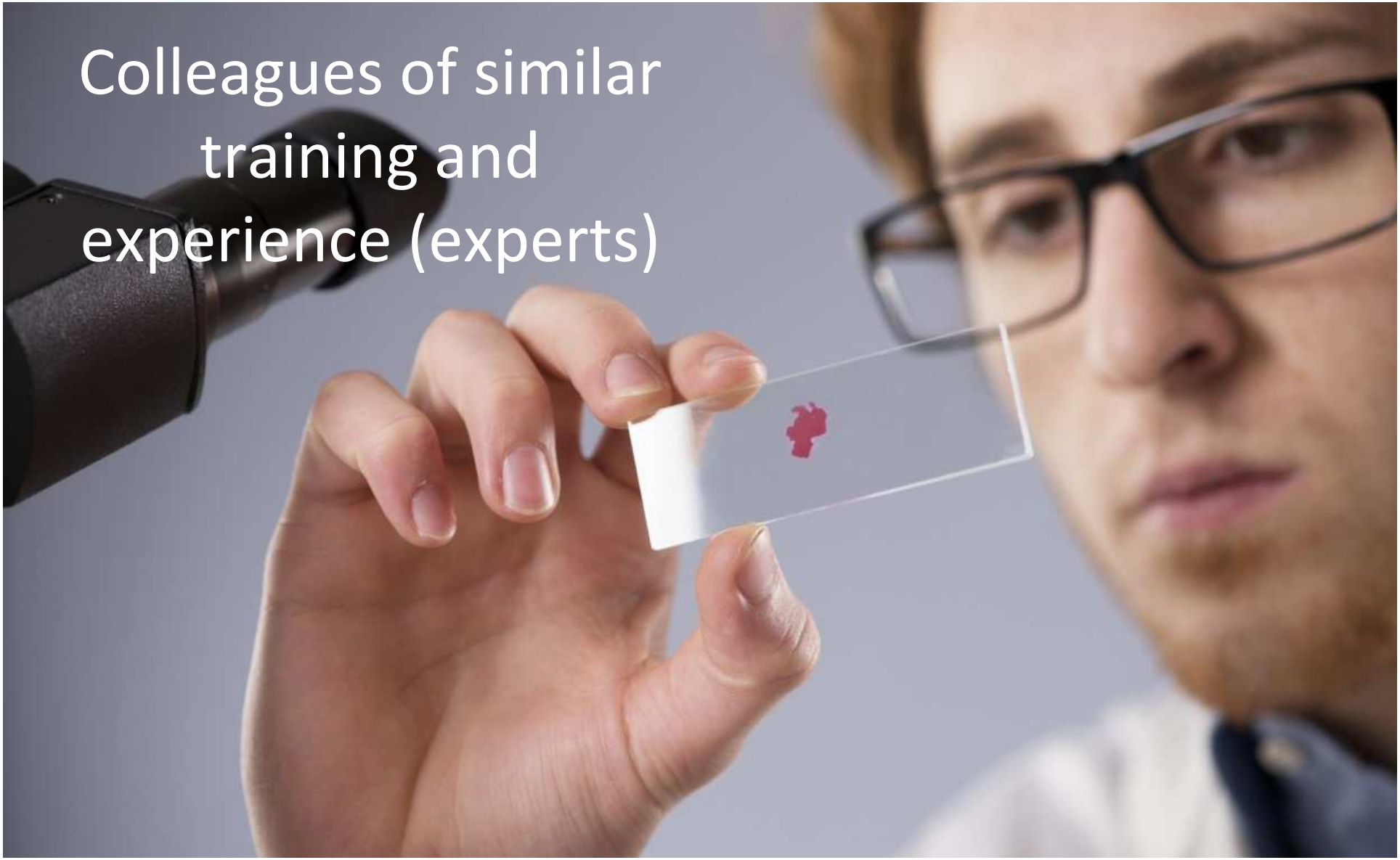
B. Failure to consult

C. Misreading/ misinterpretation of specimen

D. Not following protocols/ policies


78%
of diagnostic errors are
due to misinterpretation
or misread of specimens

Who Determines the Standard of Care?

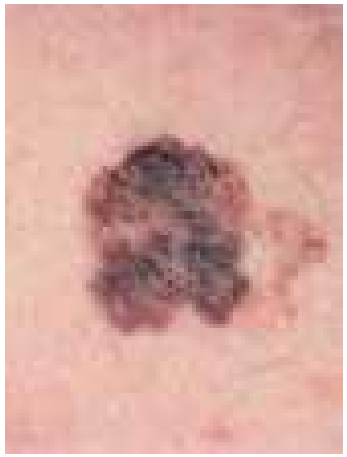


Remember

Error in Judgment ≠ Negligence

What Are the Top 3 Conditions to be Misdiagnosed?

1. Neoplasms / diseases of the breast
2. Neoplasms / diseases of the digestive tract
3. Neoplasms / diseases of the skin



63% of cases involved cancer delay in diagnosis/treatment

Medicolegal Aspects of Error in Pathology

David B. Troxel, MD

• *Objective.*—To discuss the various ways error is defined in surgical pathology. To identify errors in pathology practice identified by an analysis of pathology malpractice claims.

Design.—Three hundred seventy-eight pathology malpractice claims were reviewed. Nuisance claims and autopsy claims were excluded; 335 pathology claims remained and were analyzed to identify repetitive patterns of specimen type and diagnostic category.

Setting.—All pathology malpractice claims reported to The Doctors Company of Napa, Calif, between 1998 and 2003.

Results.—Fifty-seven percent of malpractice claims involved just 5 categories of specimen type and/or diagnostic error, namely, breast specimens, melanoma, cervical Papanicolaou tests, gynecologic specimens, and system (operational) errors. Sixty-three percent of claims involved failure to diagnose cancer, resulting in delay in diagnosis or inappropriate treatment.

Conclusion.—A false-negative diagnosis of melanoma was the single most common reason for filing a malpractice claim against a pathologist. Nearly one third involved melanoma misdiagnosed as Spitz nevus, "dysplastic" nevus, spindle cell squamous carcinoma, atypical fibroxanthoma, and dermatofibroma. While breast biopsy claims were a close second to melanoma, when combined with breast fine-needle aspiration and breast frozen section claims, breast specimens were the most common cause of pathology malpractice claims. Cervical Papanicolaou test claims were third in frequency behind melanoma and breast; 98% involved false-negative Papanicolaou tests. Forty-two percent of gynecologic surgical pathology claims involved misdiagnosed ovarian tumors, and 85% of these were false-negative diagnoses of malignancy. The most common cause of system errors was specimen "mix-ups" involving breast or prostate needle biopsies.

(*Arch Pathol Lab Med.* 2006;130:617–619)

Clinical Risks
Errors of Omission or Commission

- Missed diagnosis
  - abnormality seen but not reported
  - abnormality present but not seen
    - missed on exam
    - missed on section / staining
    - technical error
    - sampling error

Clinical Risks
Errors of Omission or Commission

- Incorrect diagnosis
  - over-interpretation of findings
  - failure to consider alternative diagnosis
  - seeing what is expected, rather than what is there

In Challenging Cases, Have You Considered?

- Further exclusionary / confirmatory investigations
- Obtaining a second opinion
- Documentation of informal 2nd opinions
- Wording of the report

AJCP 2000

Consensus Conference on Second Opinions in Diagnostic Anatomic Pathology

Who, What, and When

Am J Clin Pathol 2000;114:329-335

John E. Tomaszewski, MD, FASCP (chair),[1] Harry D. Bear, MD, PhD, FACS,[2] Julia A. Connally,[3] Jonathan I. Epstein, MD,[4] Michael Feldman, MD, PhD, FASCP,[5] Kathryn Foucar, MD, FASCP,[6] Lester Layfield, MD,[7] Virginia LiVolsi, MD, FASCP,[8] Ronald L. Sirota, MD, FASCP,[9] Mark H. Stoler, MD, FASCP,[10] and Robin E. Stombler[11]

Am J Surg Pathol 2008

- ‘Mandatory second opinion in surgical pathology referral material: clinical consequences of major disagreements’
  - Second opinion surgical pathology
  - 2.3% major diagnostic disagreements

Consider 2nd opinion

- Do the pathology findings correspond with the referring MD's clinical impression?
- Highly significant diagnosis with irreversible surgery?
- Rare disorder
- Problematic cases

Legal Actions Pathologists:
Administrative Issues

- Non-compliance with existing fail safe system
  - Mix-up specimens/ reports/ cell contamination

ERCI 2014

ECRI 2014

ECRI Institute's Top 10 Patient Safety Concerns for 2014

1. Data integrity failures with health information technology systems*
2. Poor care coordination with patient's next level of care
3. Test results reporting errors
4. Drug shortages
5. Failure to adequately manage behavioral health patients in acute care settings
6. Mislabeled specimens
7. Retained devices and unretrieved fragments*
8. Patient falls while toileting
9. Inadequate monitoring for respiratory depression in patients taking opioids
10. Inadequate reprocessing of endoscopes and surgical instruments*

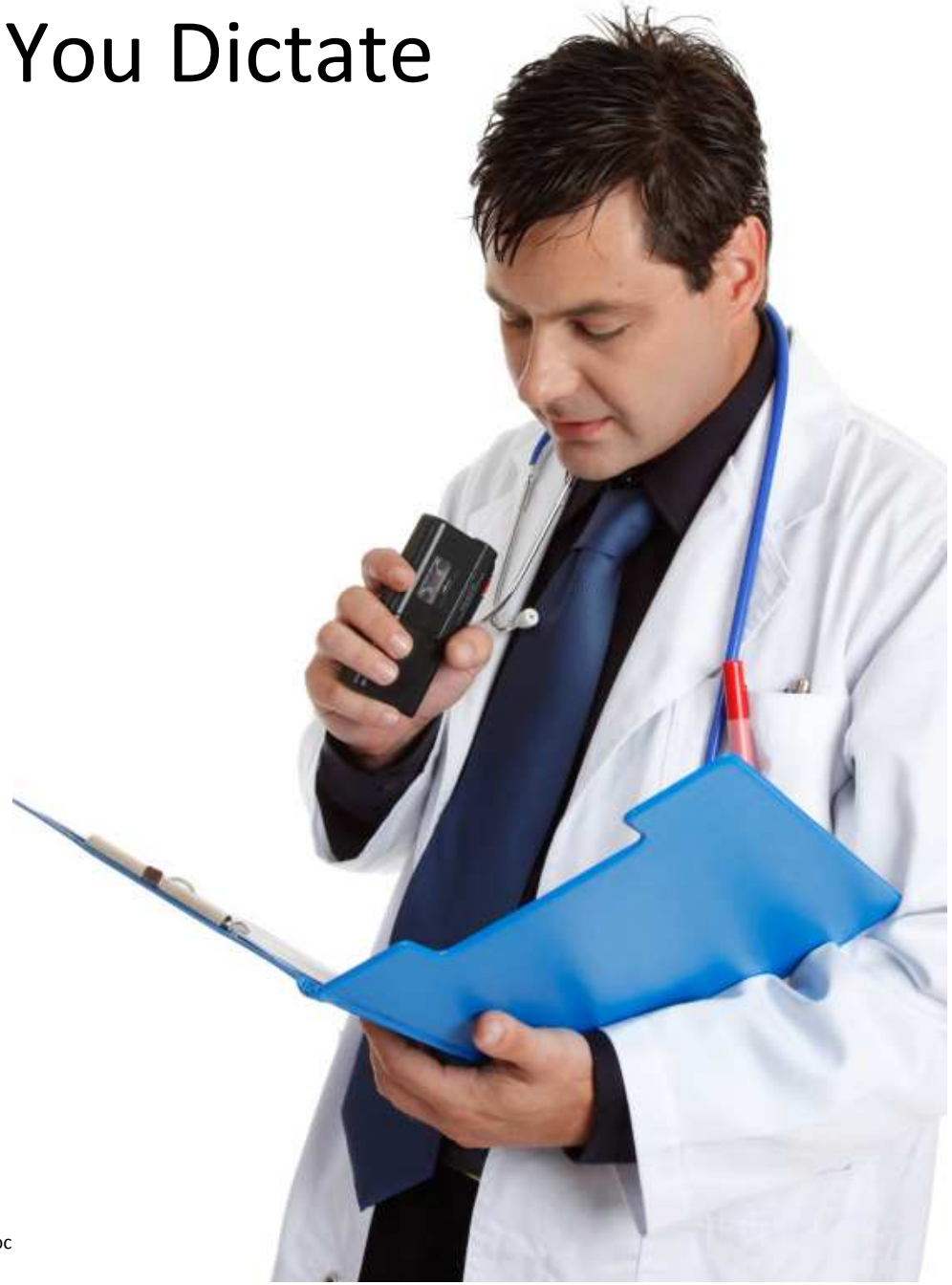
15 % of cases involved a mix-up of specimens/slides

- Mix-up of slides
- Mislabelling of specimens
- Lack of quality control measures
- Failure to comply with existing laboratory processes

In Challenging Cases, Have You Considered?

- Further exclusionary / confirmatory investigations
- Obtaining a second opinion
- Documentation of informal 2nd opinions
- **Wording of the report**

Be Careful What You Dictate



Wording your reports

"Diagnostic for metastatic squamous cell carcinoma"

Experts Would Have Reported :

" Highly atypical squamous cells suspicious for squamous cell ca:
Recommend biopsy"

Trends in Pathology Malpractice Claims

David B. Troxel, MD

Claims are frequently won or lost on the basis of the quality of the medical record. The pathology report should document the rationale for critical decision making. An incorrect diagnosis is easier to defend when the report reflects the thinking of a thoughtful and well-informed pathologist. In addition, claims are typically

Am J Surg Pathol 2012;36:e1–e5

Consider in reports

- Define pathological terms
- Discuss DDx for challenging cases
- Document recommendations for follow-up tests or treatment
- Document verbal consultations
- Document what/ whether clinical info provided

Am J Surg Pathol 2012;36:e1–e5

Reports consider:

- If provisional dx until tests/ consult available
- Provide supplemental report if NB new info available after initial report
- Document interdepartmental 2nd opinions on new malignancies , diagnostic challenges, uncommon dx (bone, soft tissue tumors)

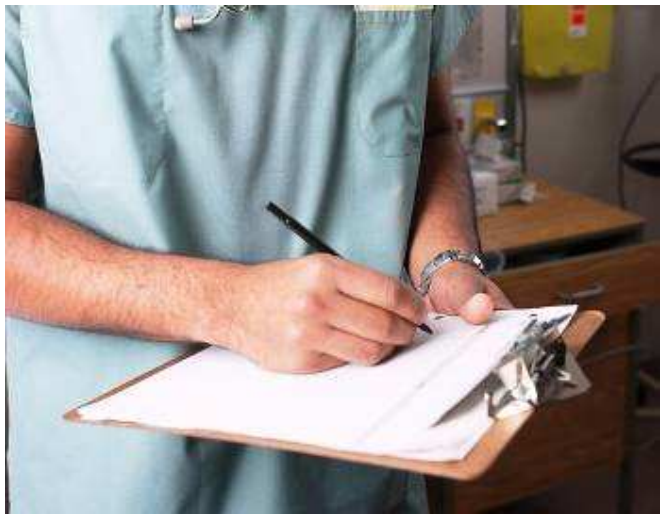
Am J Surg Pathol 2012;36:e1–e5

Postanalytic errors included a transcription error and reports or diagnoses allegedly not called to the attention of or received by the clinician. It is my impression that this allegation is increasing, and my speculation is that it may increase still more as we transition to the electronic health record. It is important to document and date all phone calls or contacts with clinicians in the pathology report, the medical record, or both.

Am J Surg Pathol 2012;36:e1–e5

Documentation of discussions

- Documentation of informal 2nd opinions
- Document calls to clinicians re substantive changes
- Document telephone advice and communications with other HCP



Second Opinion

Could I also get your opinion on this case?
33 y.o… foot lesion

I think it's a Spitz nevus - how would you comment on adequacy of excision ?

Thanks

As we discussed, I think that this is a nodular melanoma.

I would be interested in knowing how long it has been present.

Risk management

- Are there clear policies and procedures
  - handling, labeling, processing and reporting of tissue specimens?
- Requisition contain the pertinent clinical and specimen information as well as the correct patient identifiers?
- Do the patient identifiers on the specimen being examined match the requisition and the final pathology report?

Teaching Tips

- If in doubt get another opinion
- Would deeper cuts, special stains help?
- Is there sufficient information on the requisition?
- Is the specimen adequate?
- Is the expert qualified to judge the care?
- Document your DDx, evidence for Dx, recommendations, discussions with colleagues

Pathologist as Advocate

- Advising authorities of needs
  - New procedures in literature
  - Reported deficiencies of current procedures / policies
  - Equipment deficiencies / improvements
  - Safety issues for patients, staff

Put it in writing!

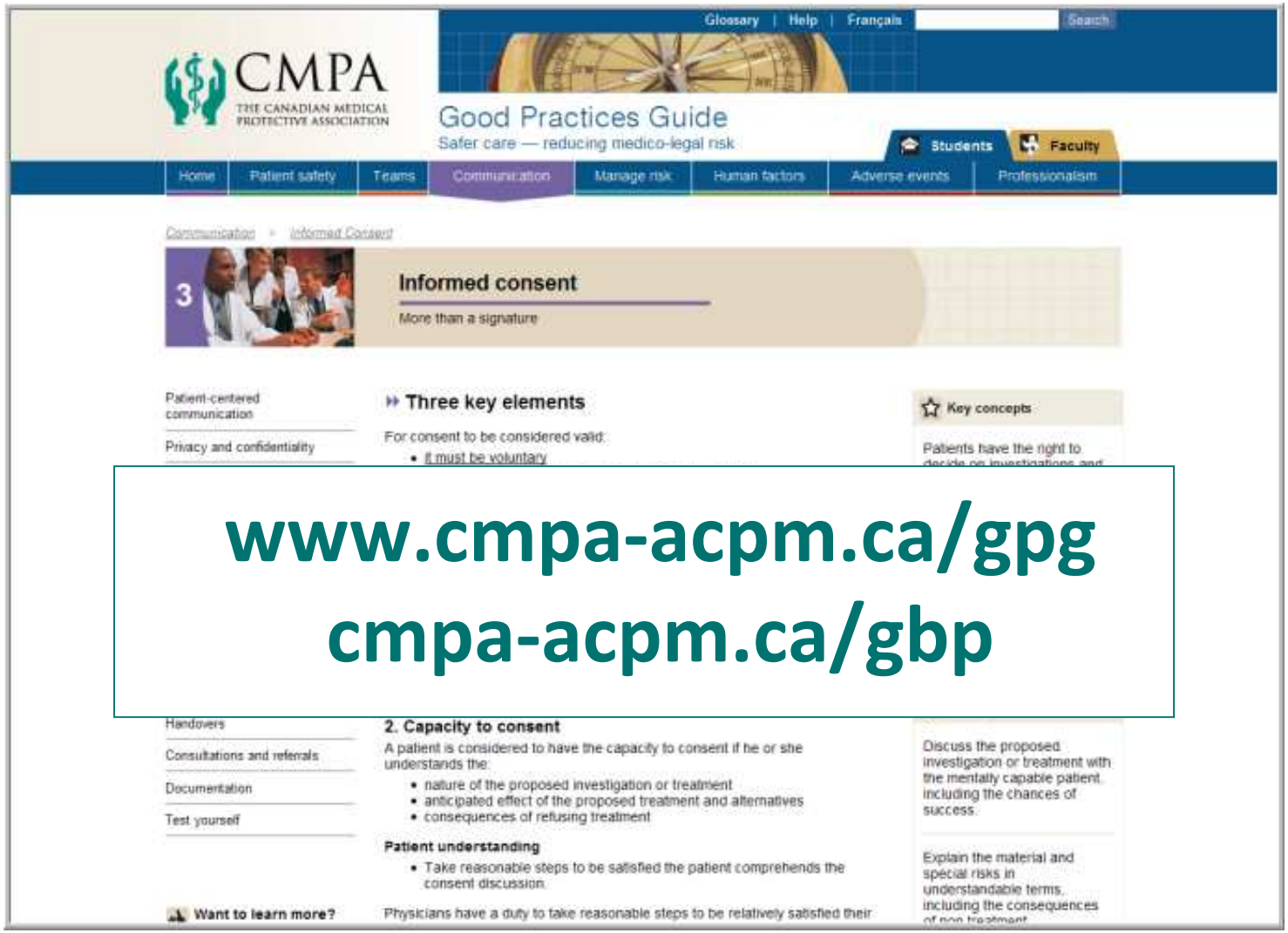
Memo

In view of October 3, 1999 Toronto Star cover story (see attached article "Agony of a cancer test mix-up") re problems of 'pick-up' at Sunnybrook, I recommend that we proactively take preventative steps, including raising awareness of the serious consequences of this type of error among tech's, histotechnologists and pathologists.

Bottom Line

- Wrong diagnosis ≠ equal negligence
- Consider second opinion in challenging cases
- Consider speaking with referring MD if diagnosis unclear or clarification needed
- Follow policies to prevent mix-ups with specimens/reports

The CMPA Good Practices Guide



The CMPA Provides Multi-channel Access to Information

- NEW! @CMPAmembers
- NEW! CMPA Perspective digital edition
- NEW! CMPA eBulletin
- CMPA Perspective print edition
- CMPA website

CMPA
RISK
MANAGEMENT
EDUCATION

1-800-267-6522

@cmpamembers

CMPA
GOOD
PRACTICES
GUIDE

 cmpa-acpm.ca