CMPA

Medico-legal Risks in Pathology

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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 medico-legal risk for pathologists
- Incorporate two strategies to reduce risk in your lab/practice

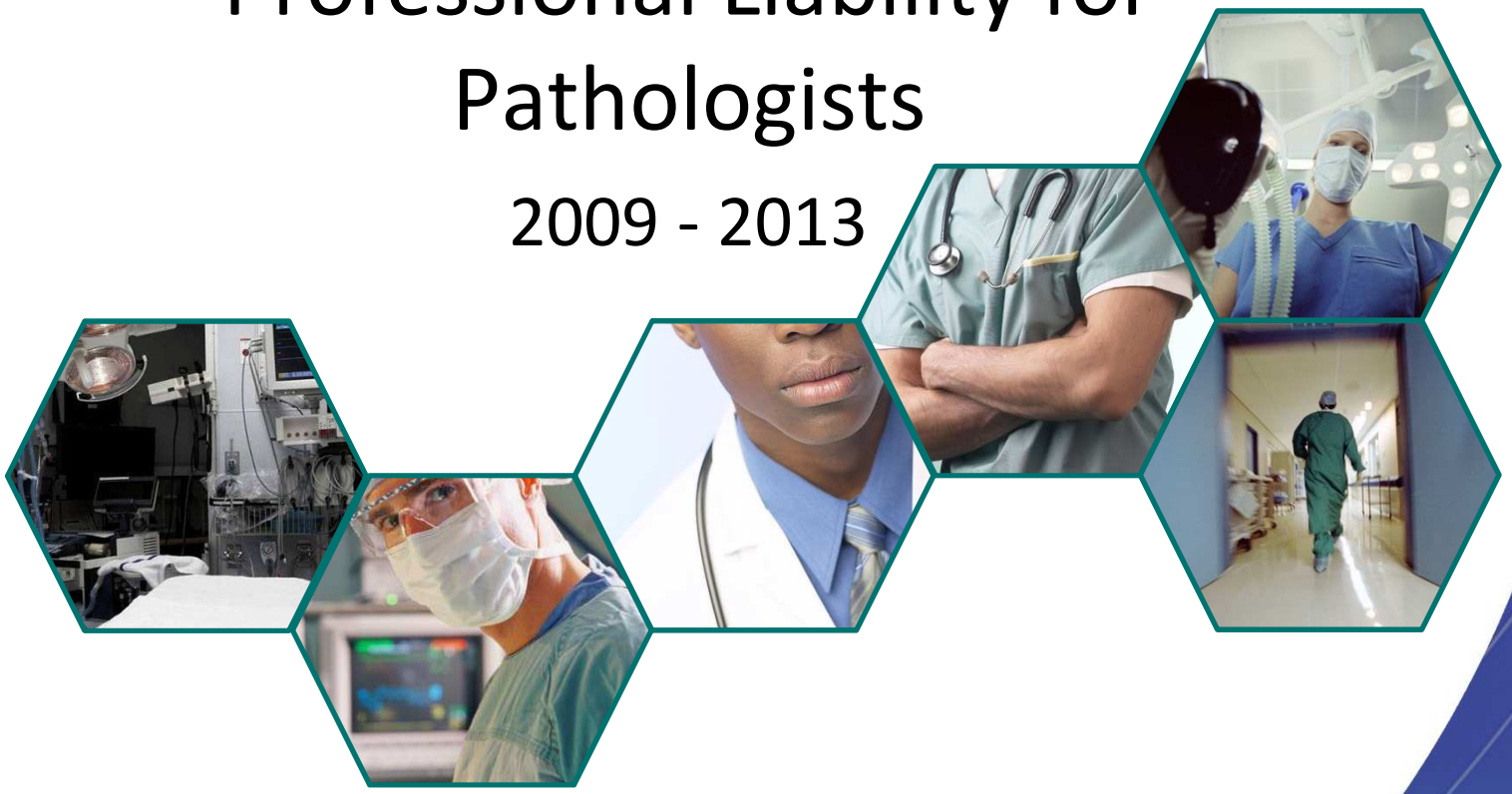
3 Ds that will affect your defensibility

- **D**elay in diagnosis
- **D**ocumentation
- **D**iligence with protocols

CMPA

Professional Liability for Pathologists

2009 - 2013



Welcome to

Who Wants to Defend a Million Dollar Legal Action ?

10	●	$1 Million
9	●	$500,000
8	●	$250,000
7	●	$125,000
6	●	$64,000
5	●	$32,000
4	●	$16,000
3	●	$8,000
2	●	$4,000
1	●	$2,000

Adapted from Teachnet.com

5 • $ 1 Million

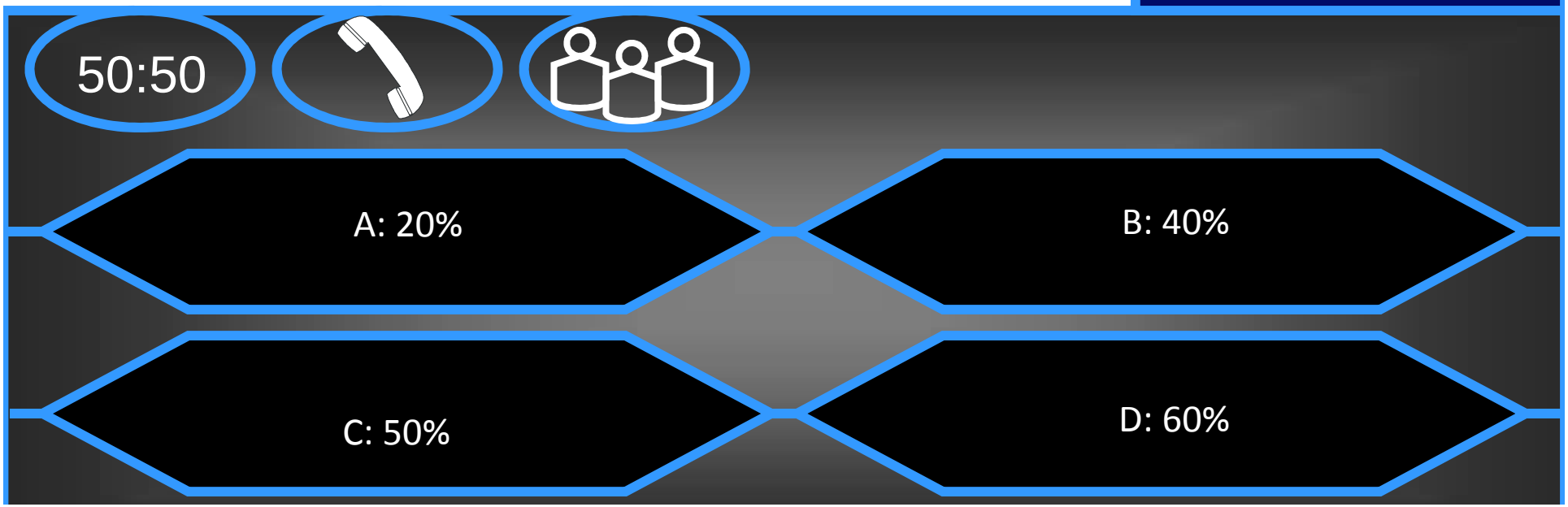
4 • $500,000

3 • $100,000

2 • $10,000

1 • $5,000

Overall about 34% of CMPA legal actions are settled. What % of legal actions involving pathologists have to be settled?



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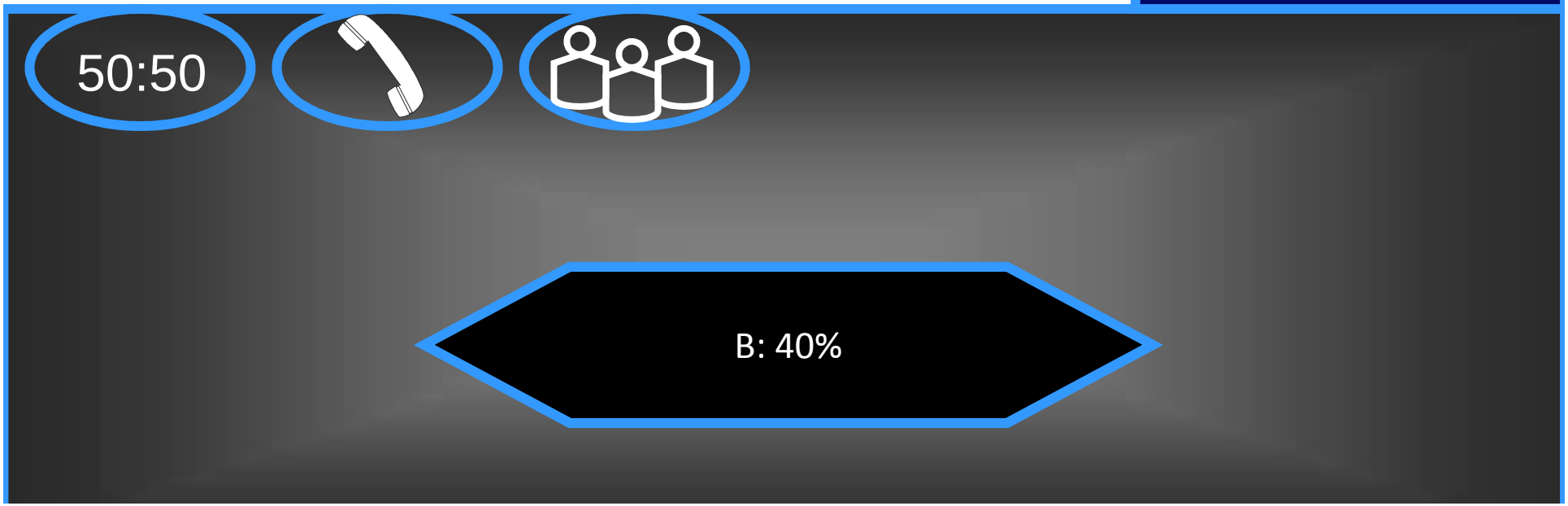
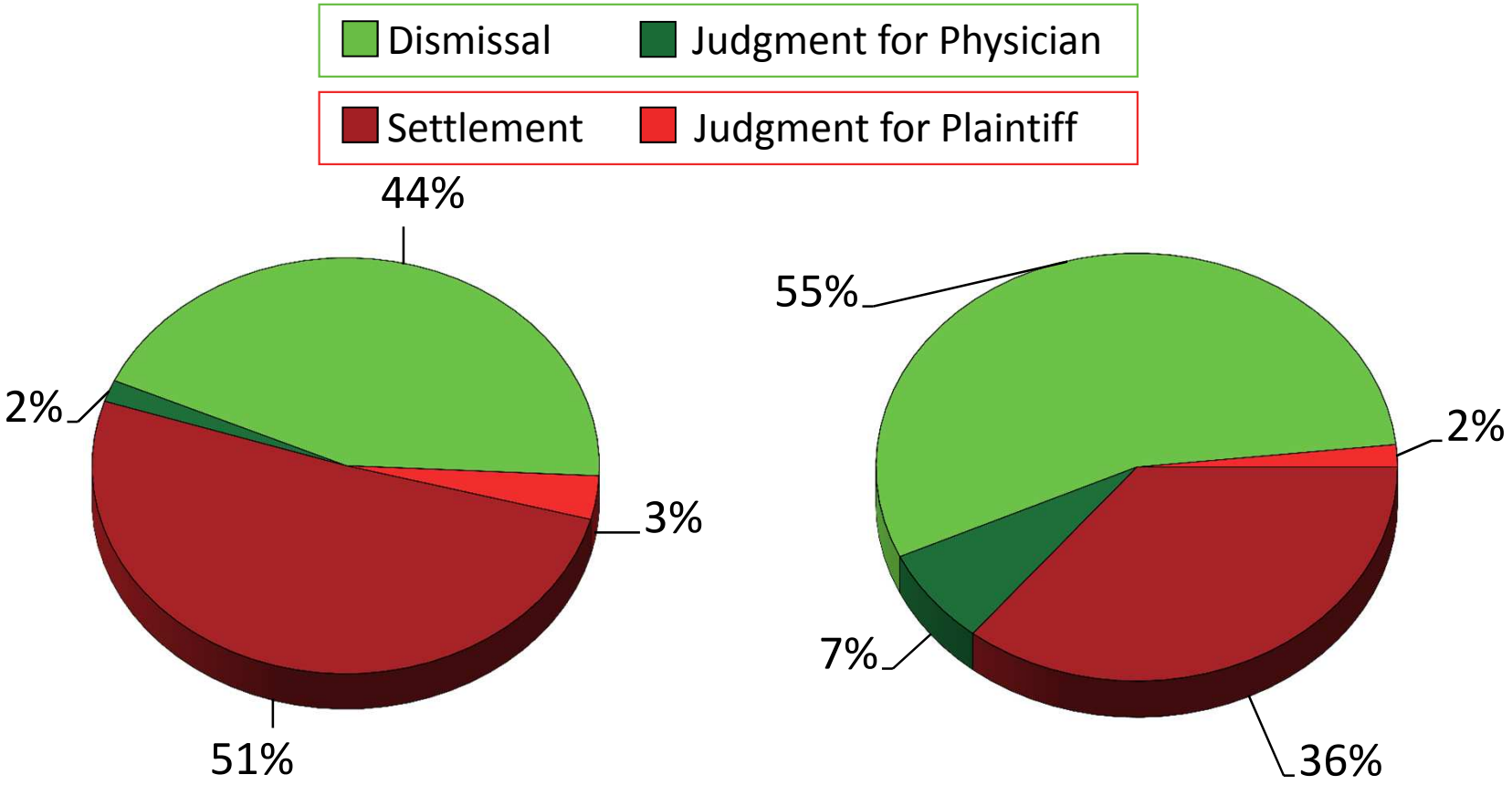


Legal Outcome - Comparison
Legal Actions Closed 2009 - 2013

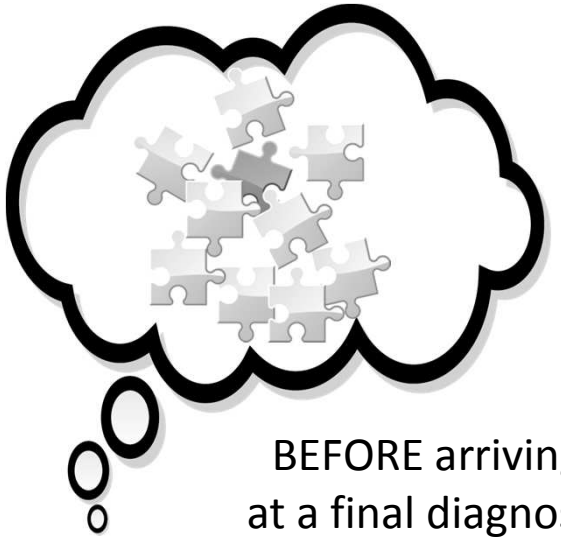


Pathologists (N = 59)

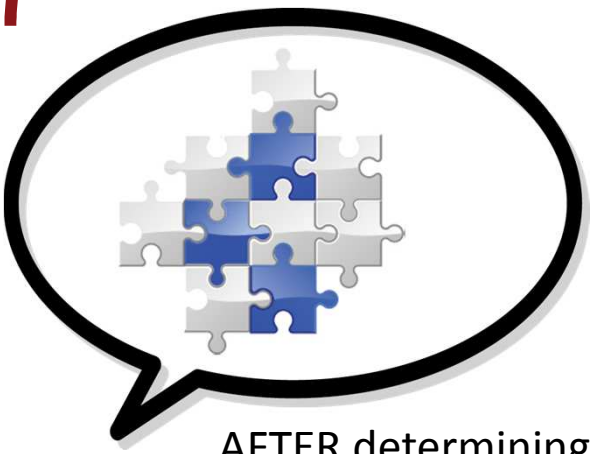
CMPA (N = 4,520)

Hindsight and Hindsight Bias

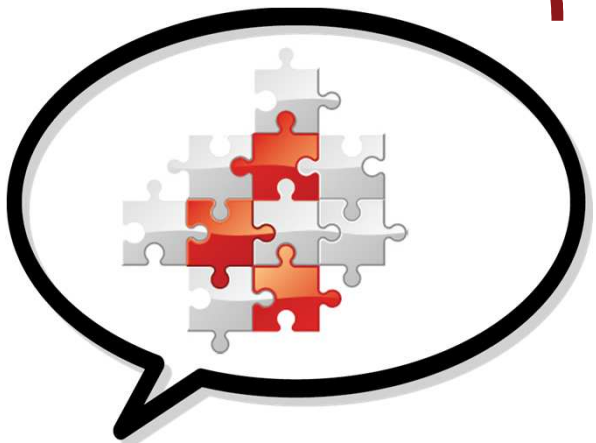
The puzzle is solved, the final diagnosis is clear



BEFORE arriving at a final diagnosis

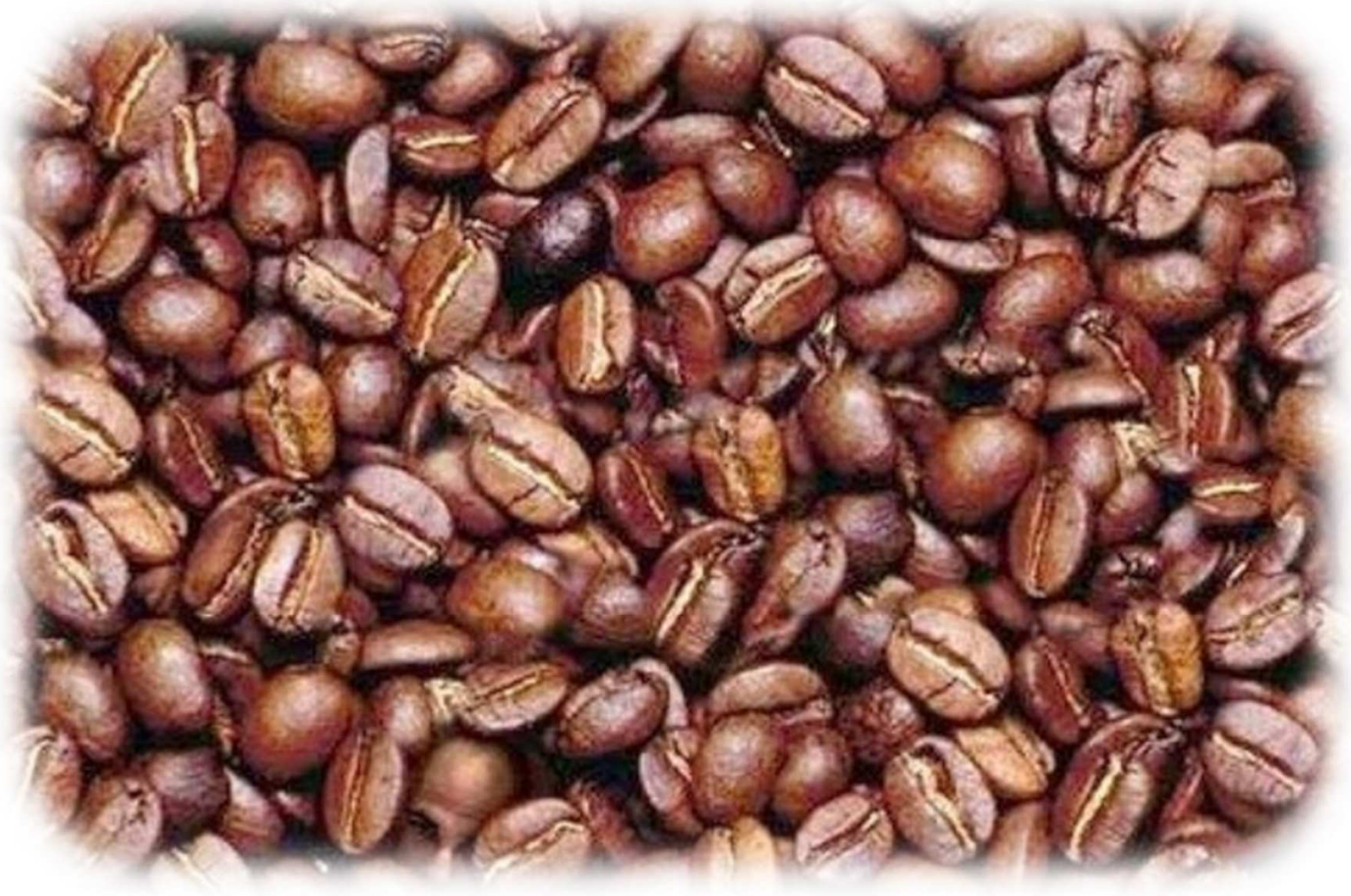


AFTER determining the final diagnosis



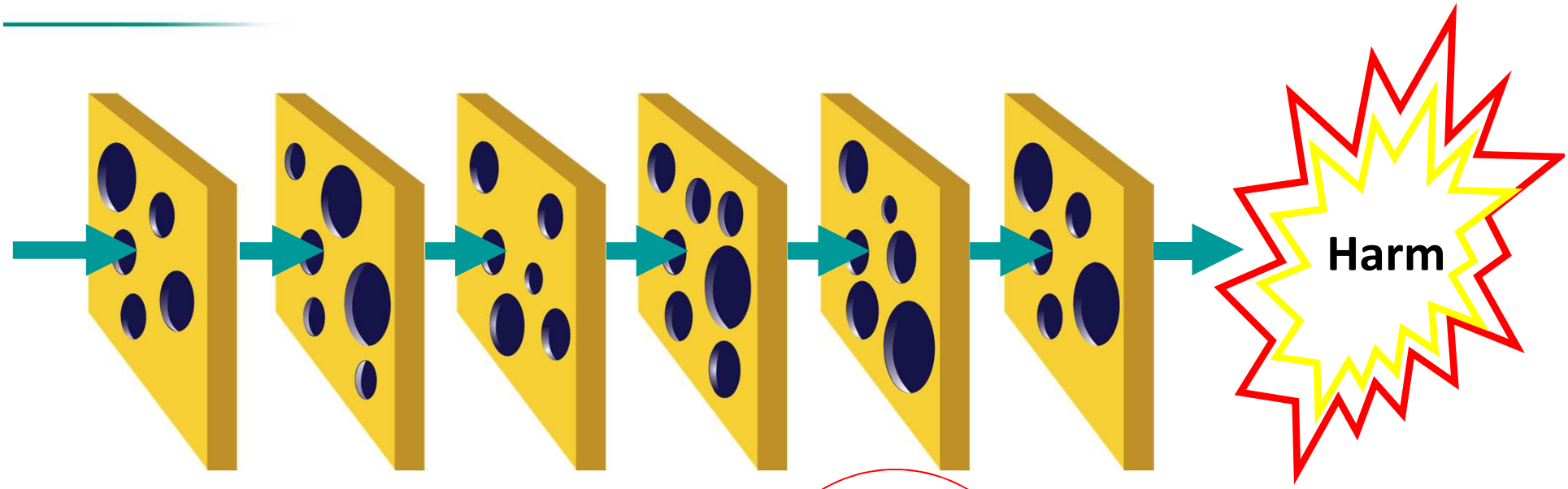
AFTER a delay in making a diagnosis or a misdiagnosis

Where is the abnormality?



Where is the abnormality?

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

In the last 5 years what % closed pathology legal actions have a catastrophic outcome for the patient?

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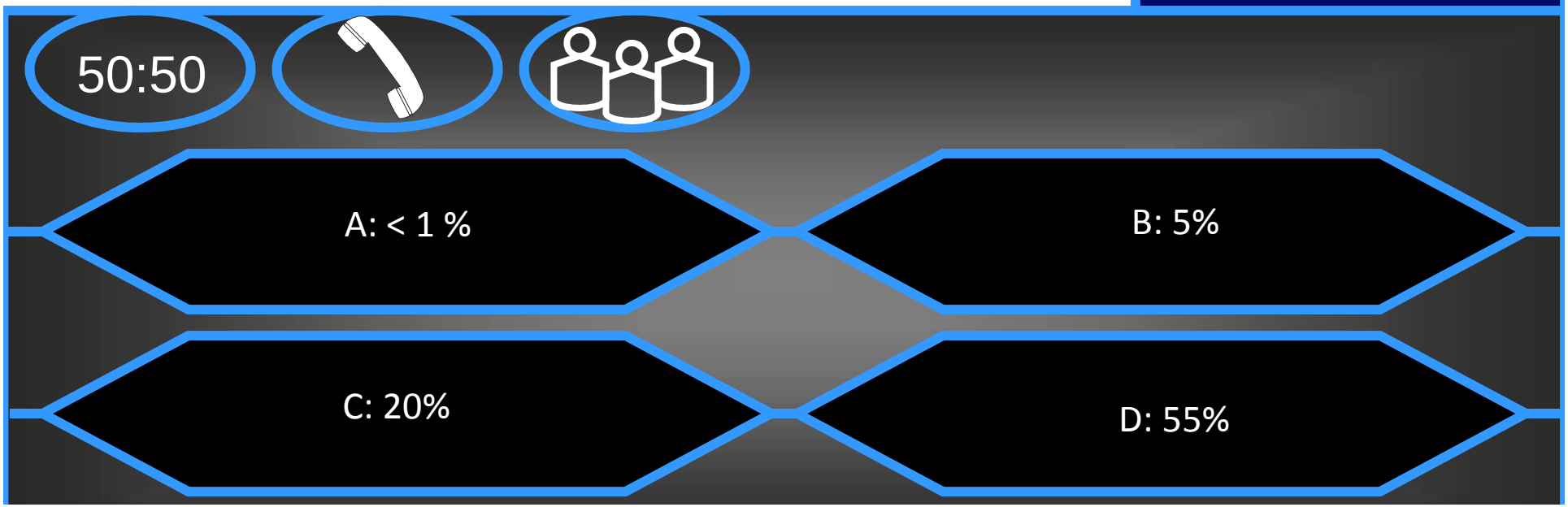

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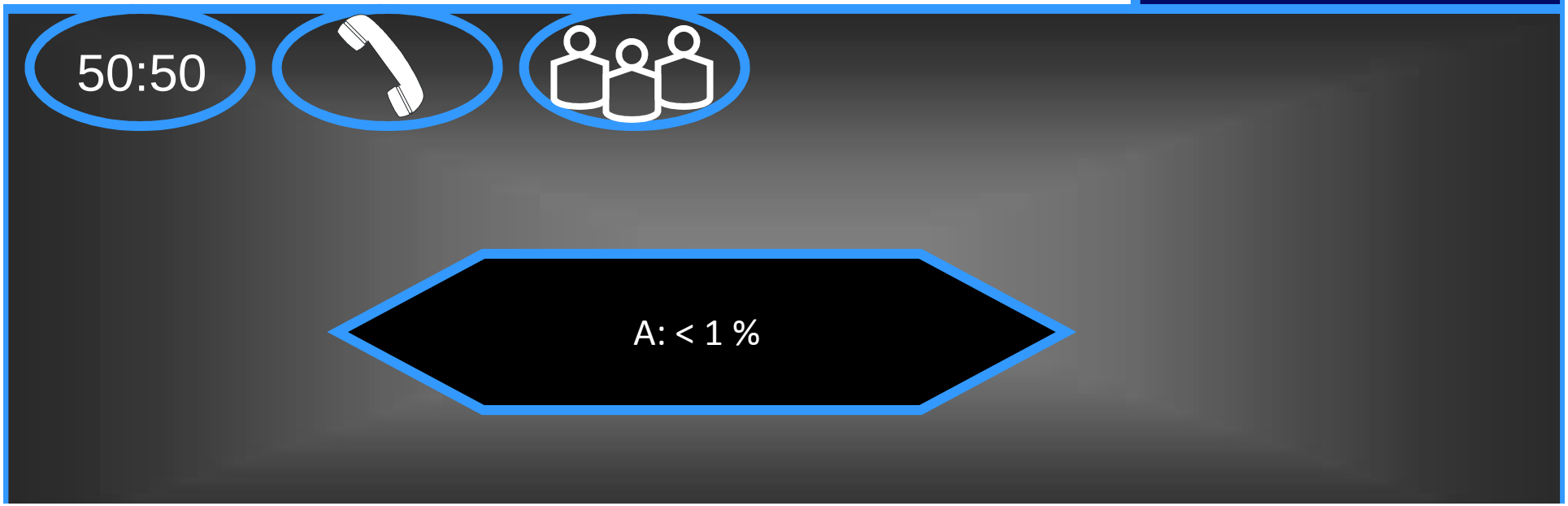
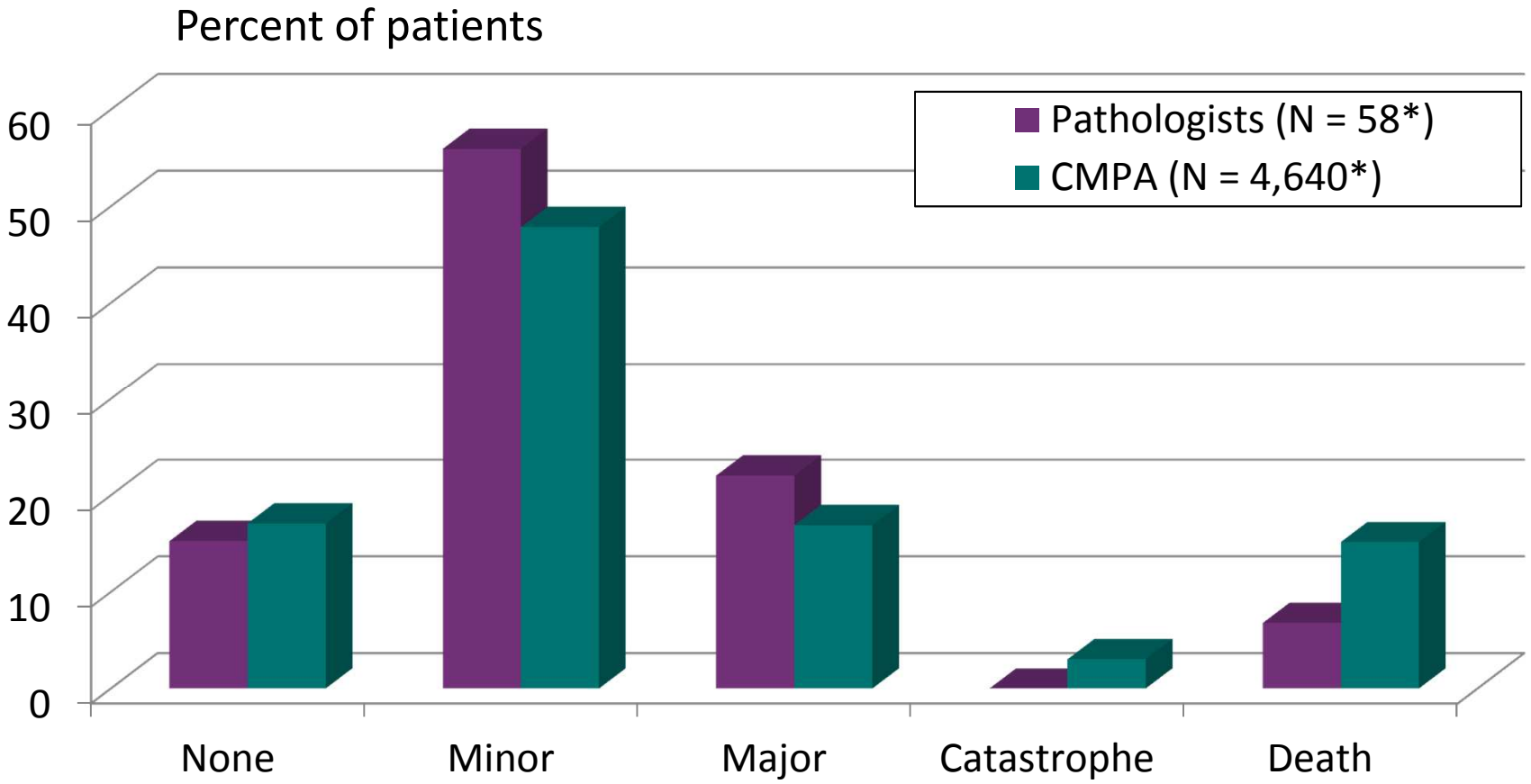


Physical Disability of Patients
Legal Actions Closed 2009 - 2013



* Number of patients

5 • $ 1 Million

4 • $500,000

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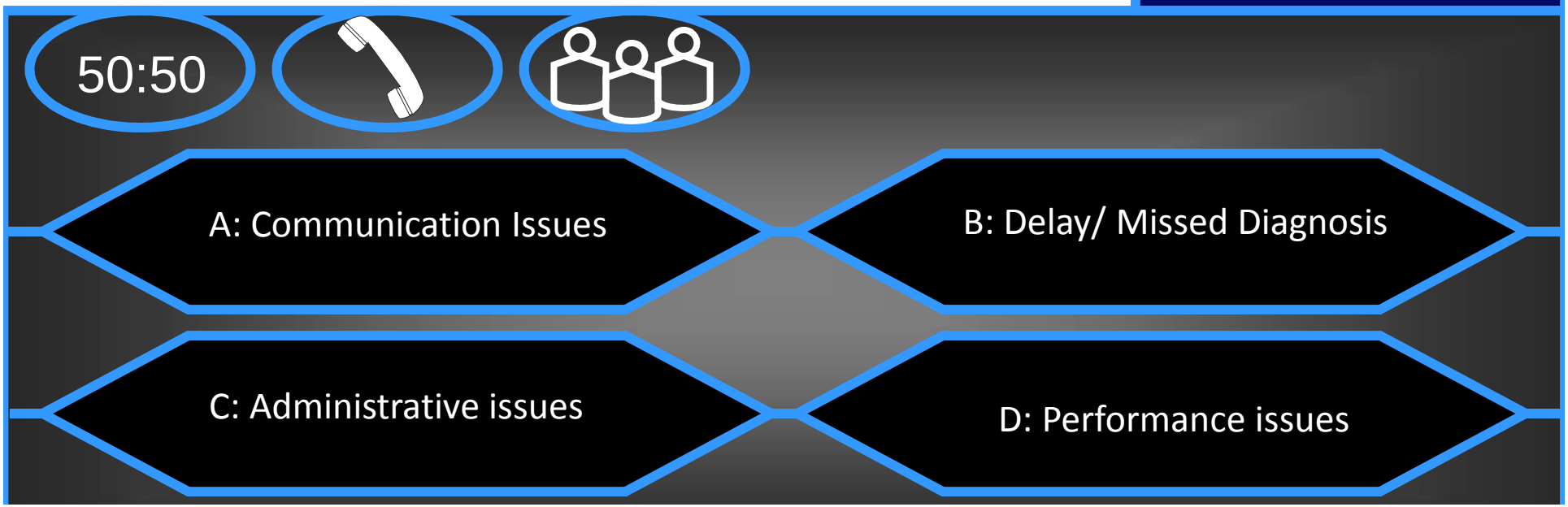
The most common critical incident in closed legal actions involving pathologist is?



The most common critical incident in closed legal actions involving pathologist is?

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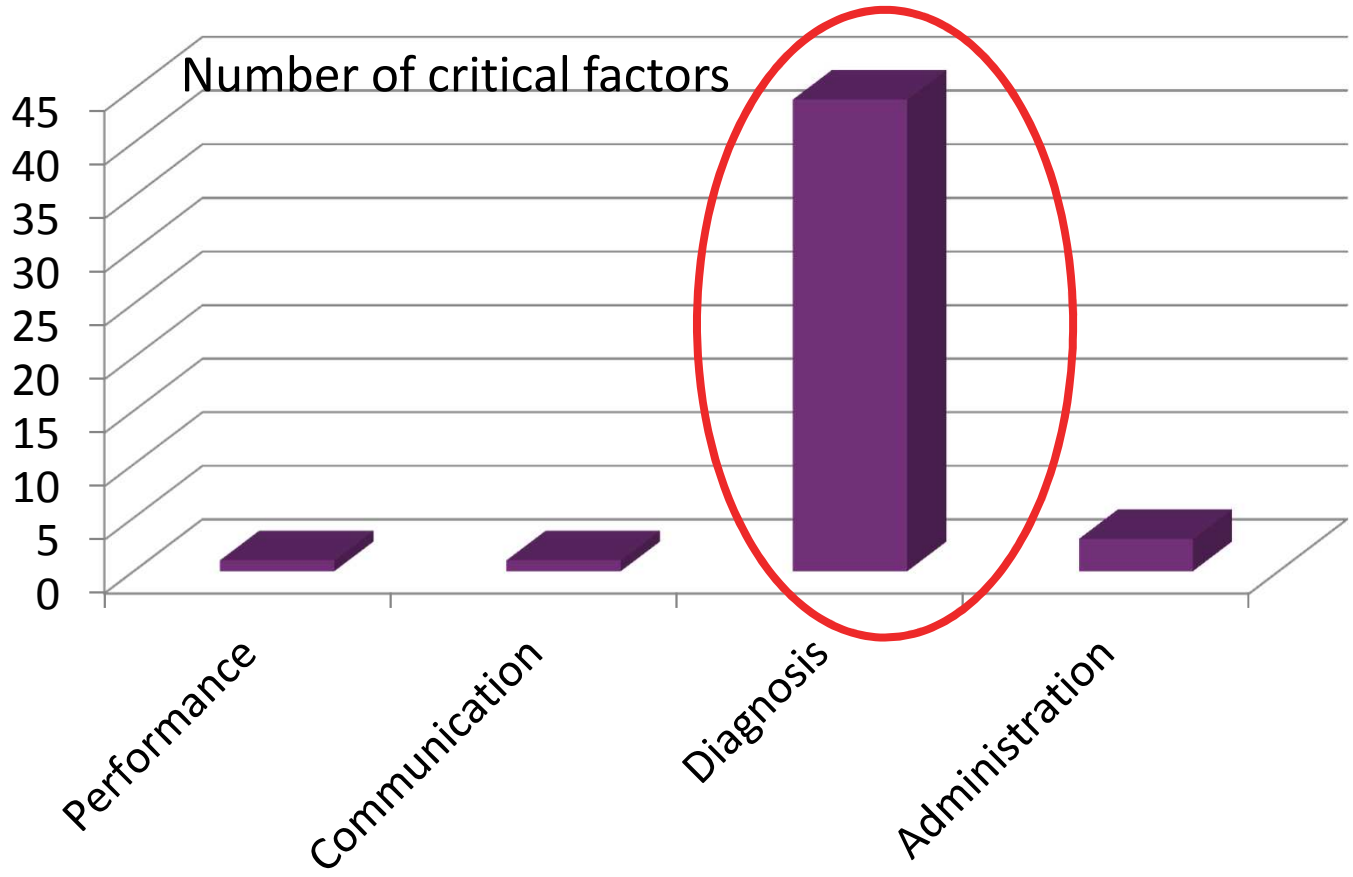
Critical Factor
59 Legal Actions Closed 2009 - 2013

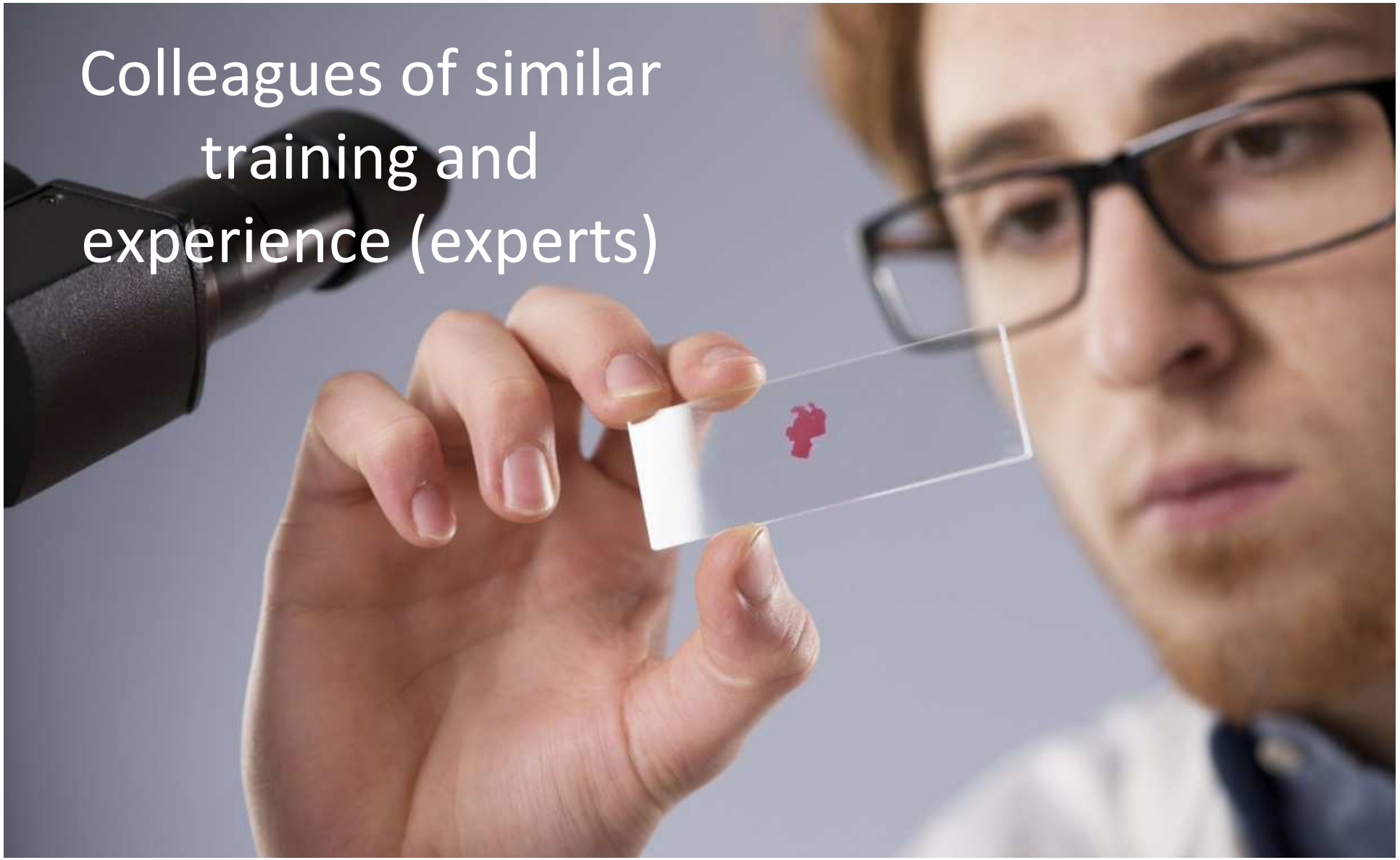


***Number of critical factors**

What Can Lead to Misdiagnosis?


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

Who Determines the Standard of Care?

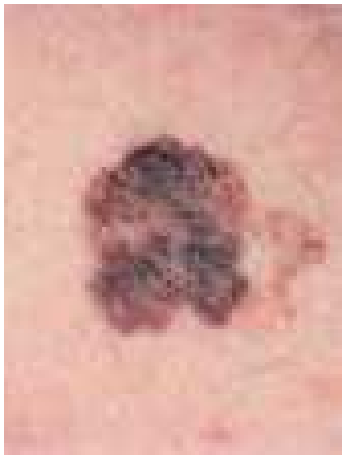


Remember

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)

Arch Path Lab Med. 2006;130:617-619

Arch Path Lab Med. 2006;130:617-619

TABLE 3. One Hundred Forty-Two Pathology Claims Closed From 2004 Through 2010

Specimen Category	Total Claims	Claims Per Year	% (#) False Negative (Cancer)	% (#) False Positive (Cancer)	% Total Claims
Miscellaneous surgical pathology	23	3.3	—	—	16.2
Gynecologic cytology	10	1.4	100% (10)	None	7.0
Breast specimens	15	2.1	40% (6)	46.7% (7)	10.6
Melanoma	17	2.4	94% (16)	6.0% (1)	12.0
Fine needle aspiration, miscellaneous	10	1.4	—	—	7.0
Lymphoma	1	0.1	—	—	0.7
Fine needle aspiration, breast	2	0.3	—	—	1.4
Clinical pathology	8	1.1	—	—	5.6
Nongynecologic cytology	3	0.4	—	—	2.1
System error	15	2.1	N/A	N/A	10.6
Gynecologic pathology	6	0.9	—	—	4.2
Sarcomas	5	0.7	—	—	3.5
Lung pathology	6	0.9	—	—	4.2
Gastric biopsy	3	0.4	—	—	2.1
BCC	5	0.7	100% (5)	—	3.5
Colon	7	1.0	—	—	4.9
Frozen section	6	0.9	—	—	4.2

From CMPA cases

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

From CMPA cases

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

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

Let’s Look at Some Cases

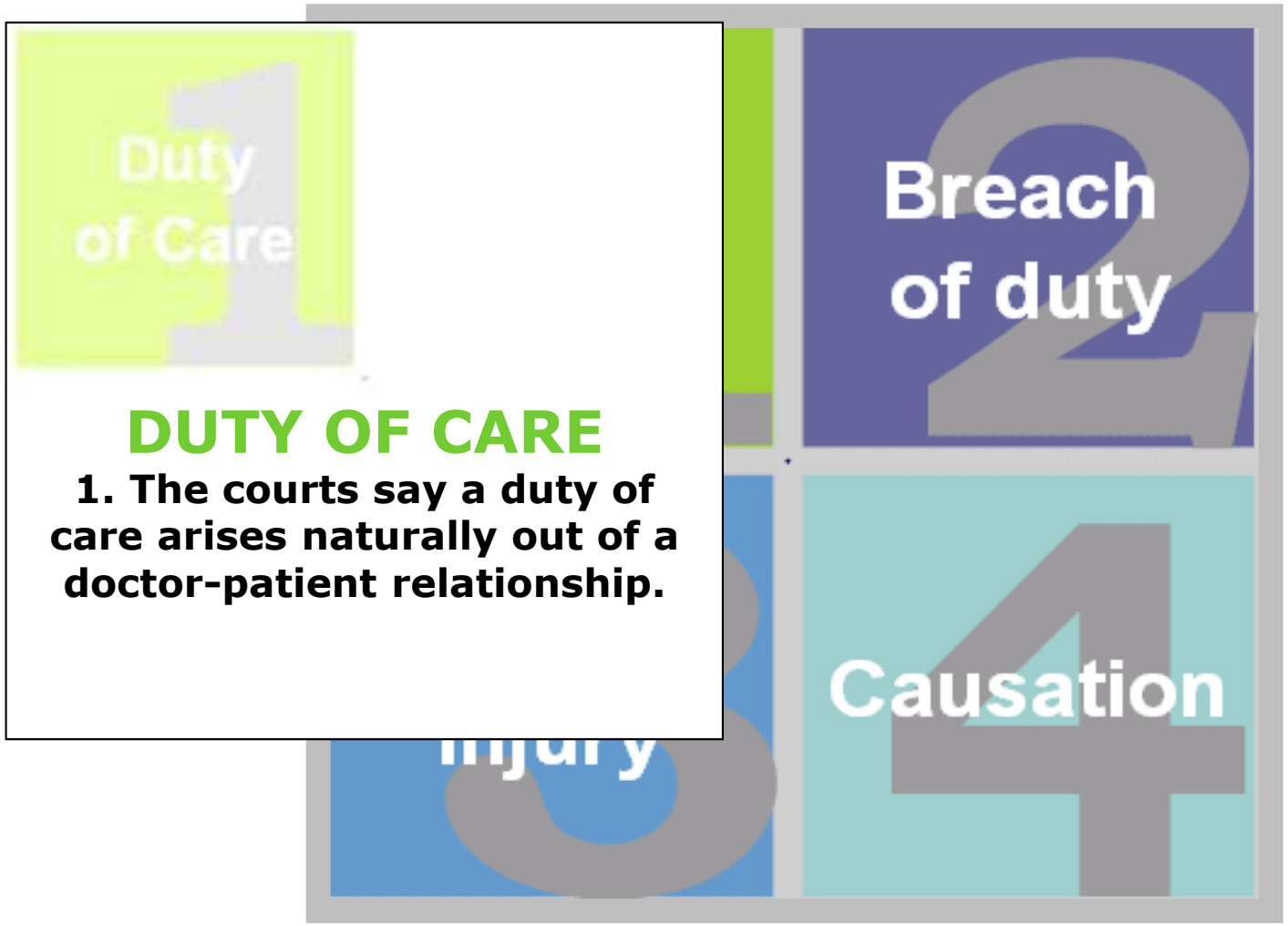
Case #1

Unable to Obtain Expert Support

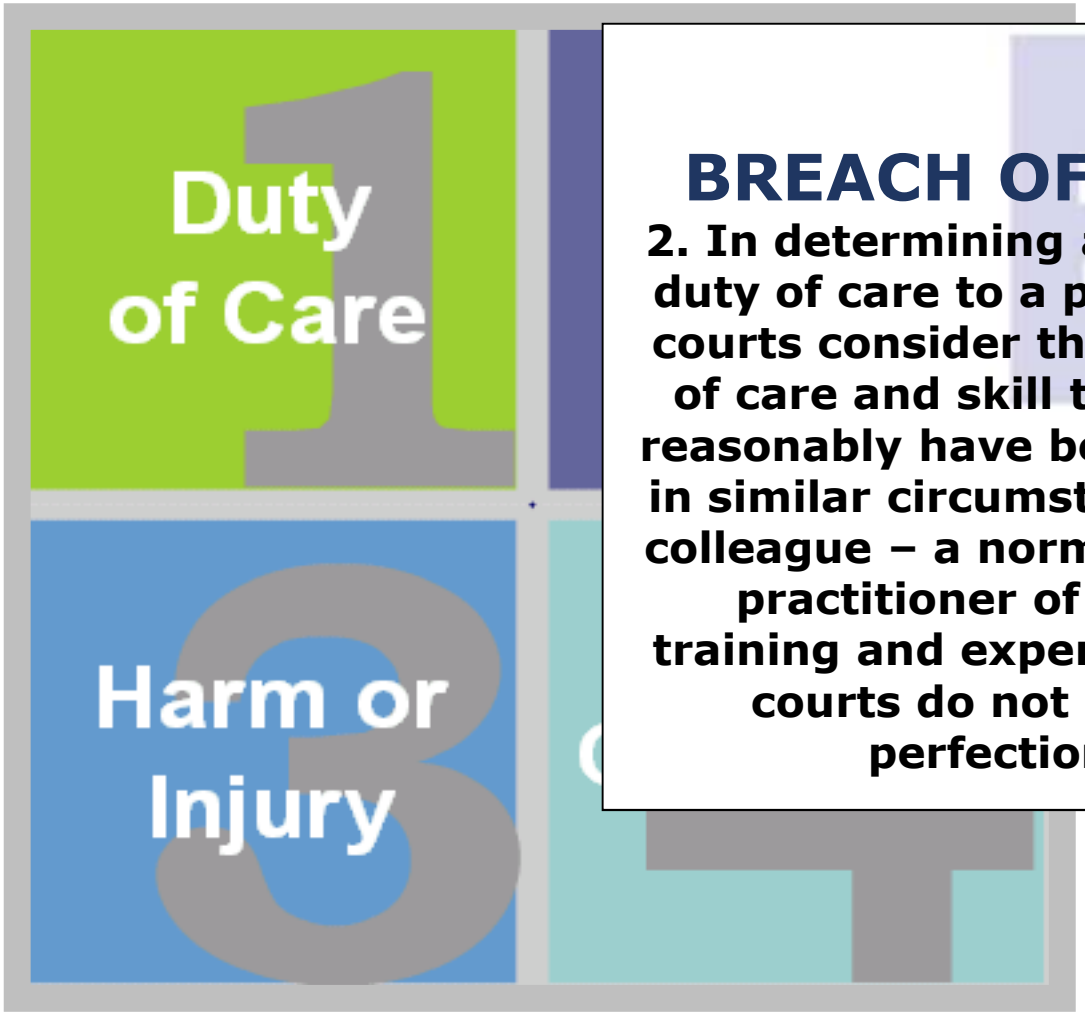
- Settled on behalf of Path1

Negligence: the Legal Concept

Negligence: the Legal Concept



Negligence: the Legal Concept



BREACH OF DUTY

2. In determining a breach of duty of care to a patient, the courts consider the standard of care and skill that might reasonably have been applied in similar circumstances by a colleague – a normal prudent practitioner of similar training and experience. The courts do not expect perfection.

Courts are generally sympathetic

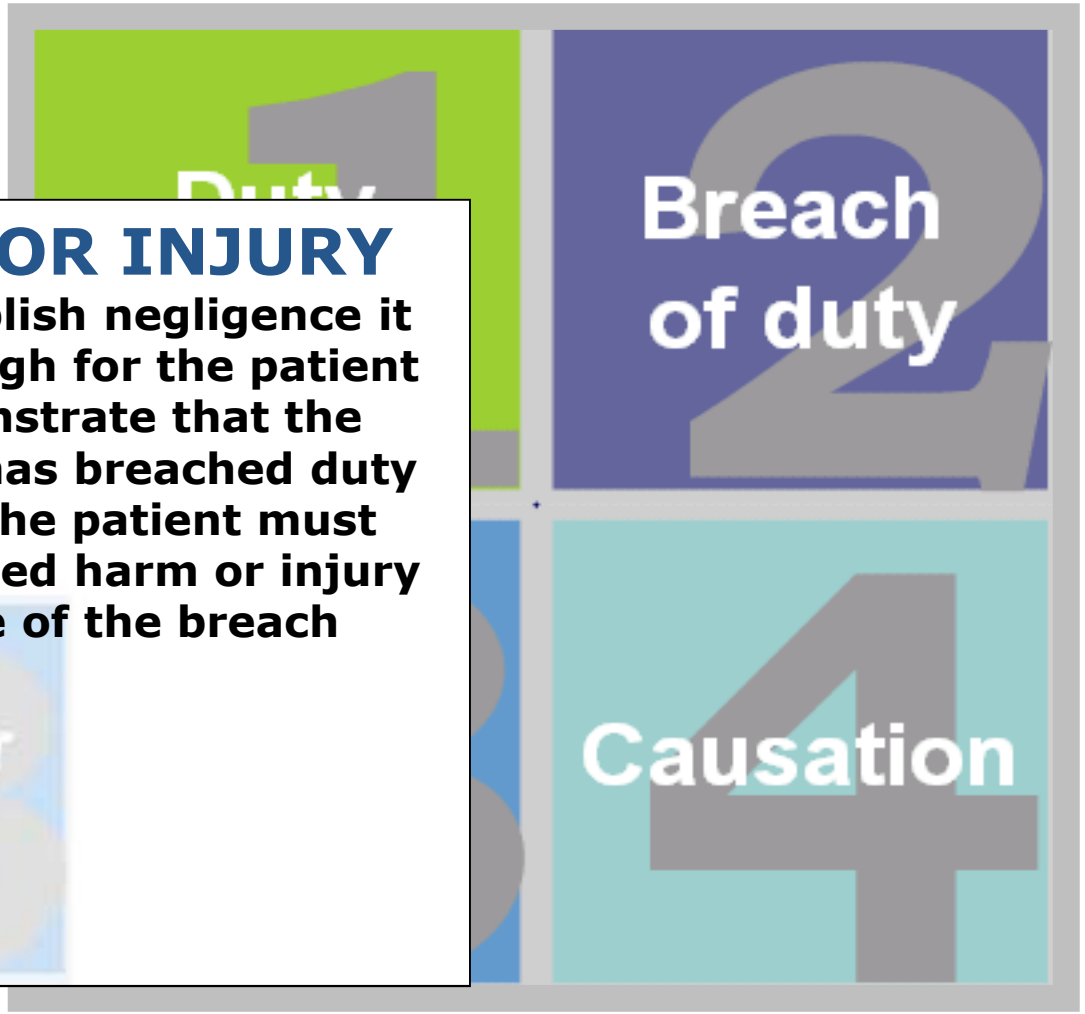
"A doctor is not expected to be infallible, only to exercise reasonable care, skill and judgment in coming to a diagnosis. If this is done, the doctor will not be held liable even if the diagnosis is mistaken"

(Picard & Robertson)

Crits v Sylvester, 1956

"Every medical practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. He is bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing, and if he holds himself out as a specialist, a higher degree of skill is required of him than one who does not profess to be so qualified by special training and ability."

Negligence: the Legal Concept

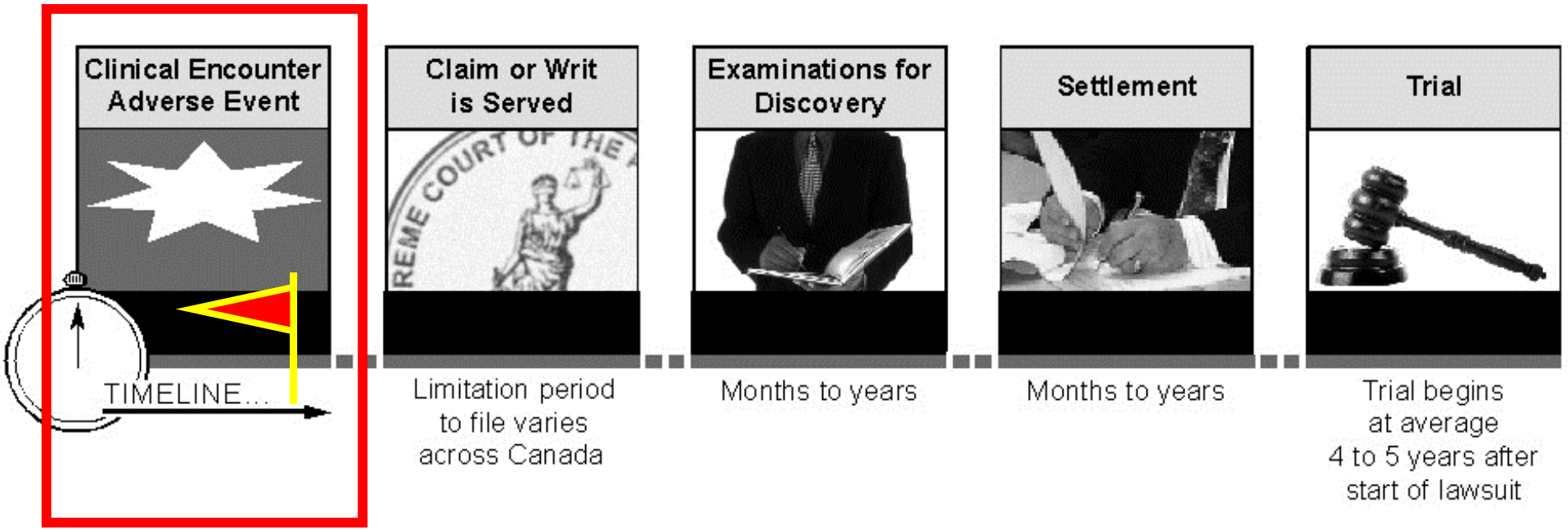


HARM OR INJURY

3. To establish negligence it is not enough for the patient to demonstrate that the physician has breached duty of care. The patient must have suffered harm or injury because of the breach

Negligence: the Legal Concept

Anatomy of a Lawsuit



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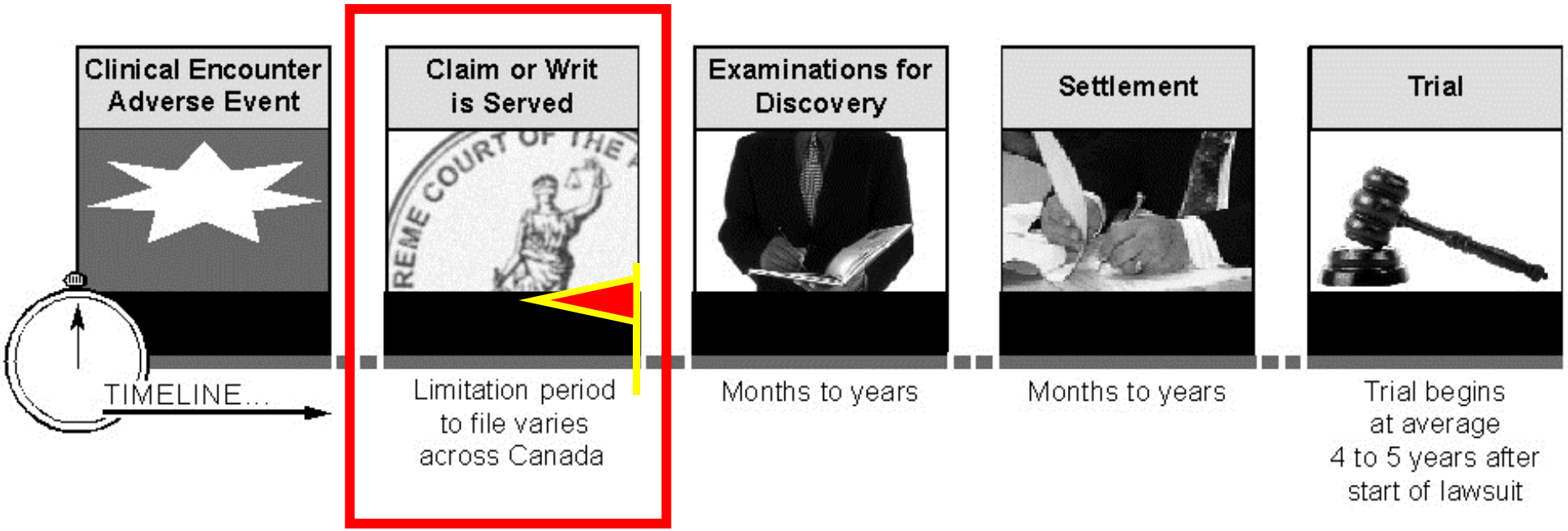
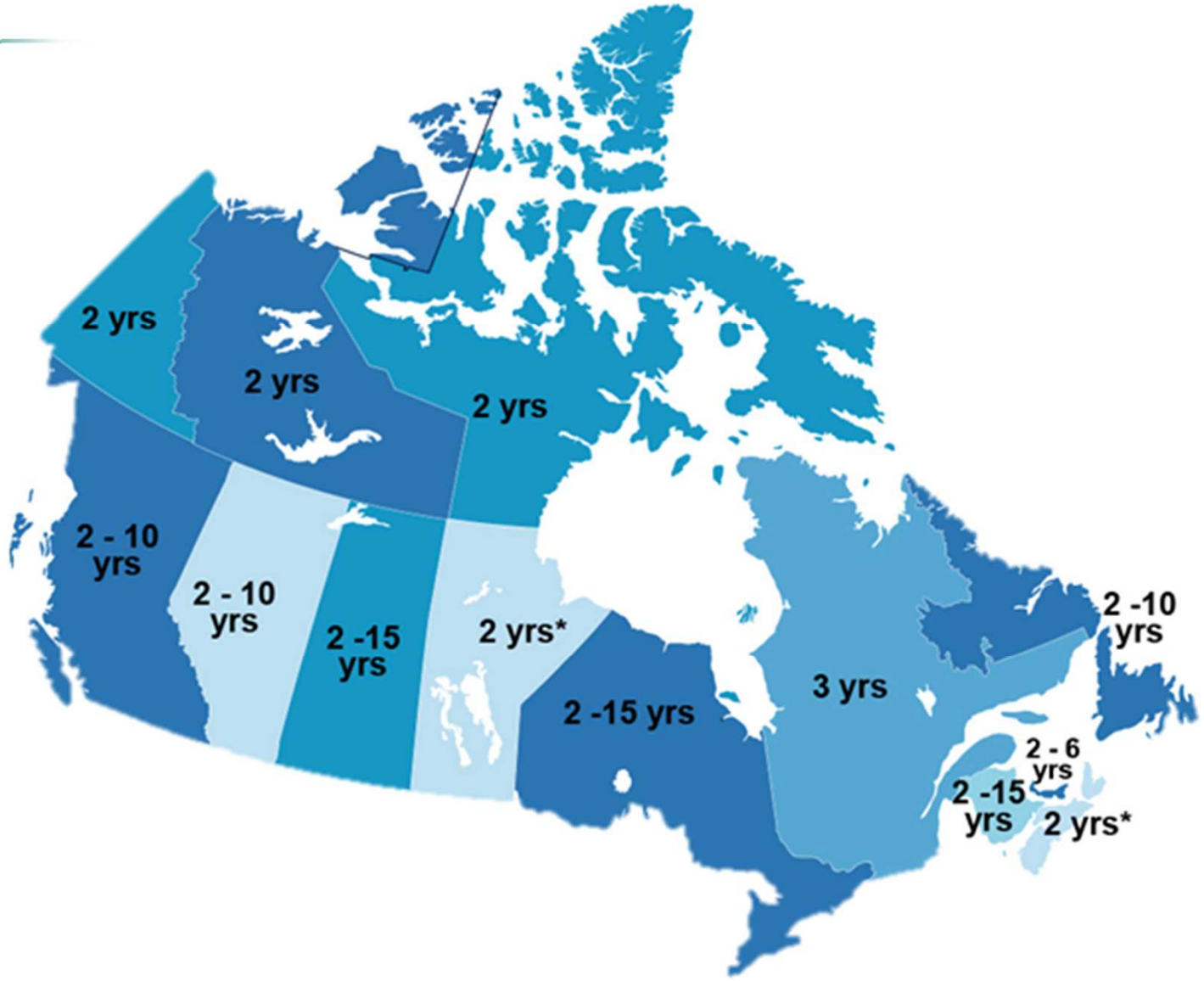


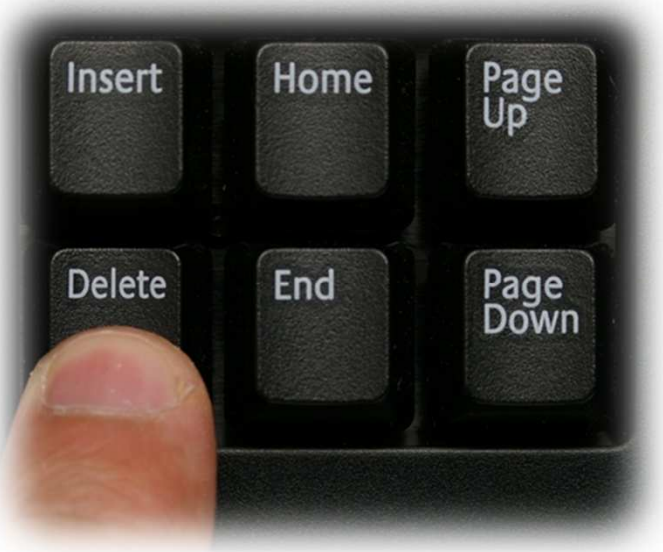
Stature of Limitations

timelines are long

Limitation Periods in Canada



What NOT to do when you get a SOC



Better yet…call the CMPA

Get a grip.

Get advice.

Take the advice.

Anatomy of a Lawsuit

Doctors' involvement in lawsuits

- As defendants
- As medical experts
- As witnesses of fact

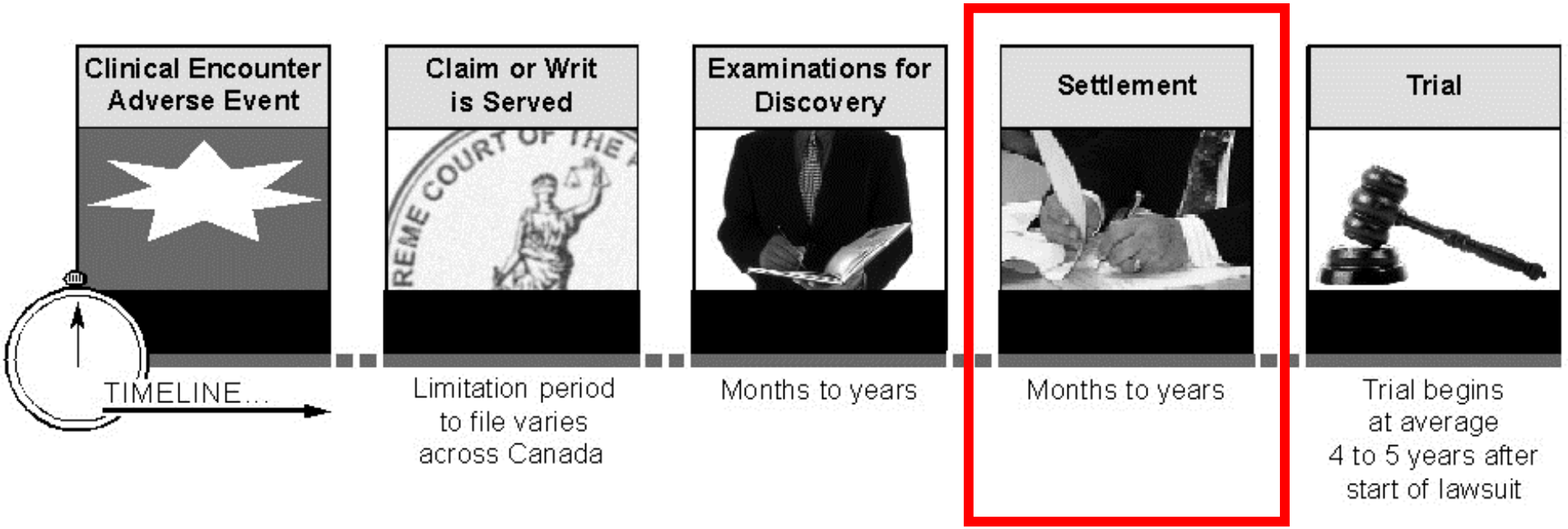
Testimony – **Fact Witness**

- Usually in the role of treating physician
- Ensure that a consent is signed
  - Even if your patient's lawyer calls
- A court summons to witness
  - Mandates release of the record and does not require consent for release
- Court trumps confidentiality to patient
- You are not required to give an "expert opinion"

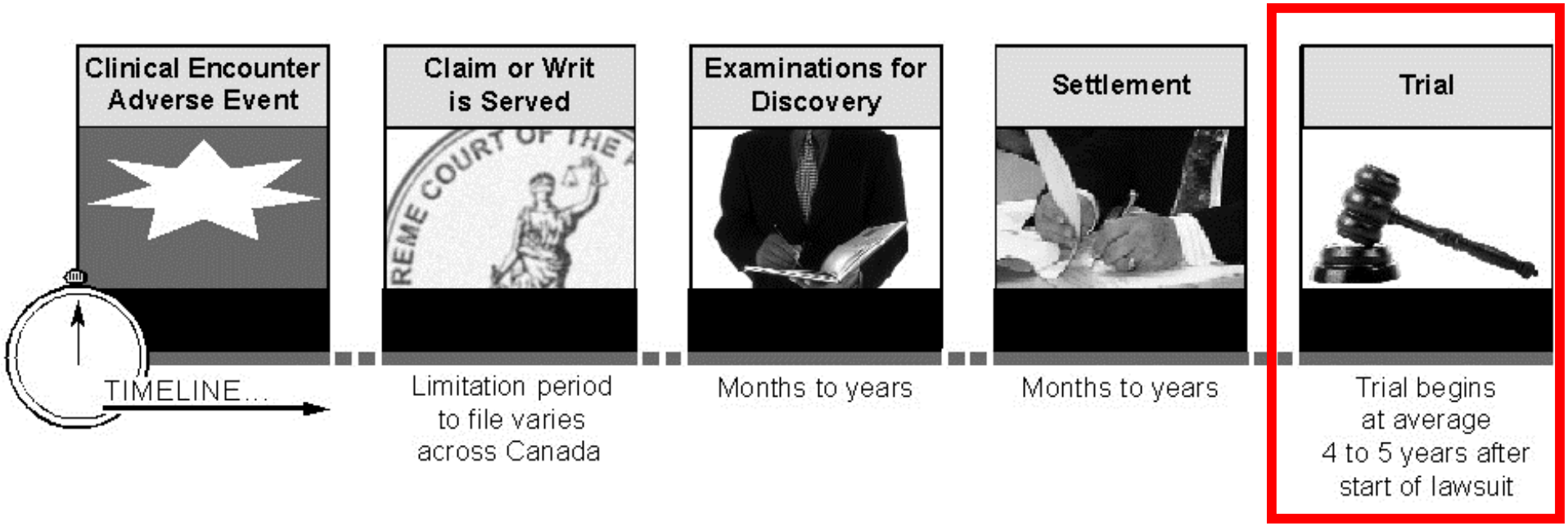
Testimony – **Expert**

- Are you really an “expert?”
- Remember the definition of “standard of care”
  - Different for generalists vs specialists
- What is your role in court?
- Duty is to the court not your “employer”

Anatomy of a Lawsuit



Anatomy of a Lawsuit



Court?!

Testimony

- “Do I have to do it?”
- The unfortunate answer is **“MAYBE”**

Case #1

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 May;32(5)732-7

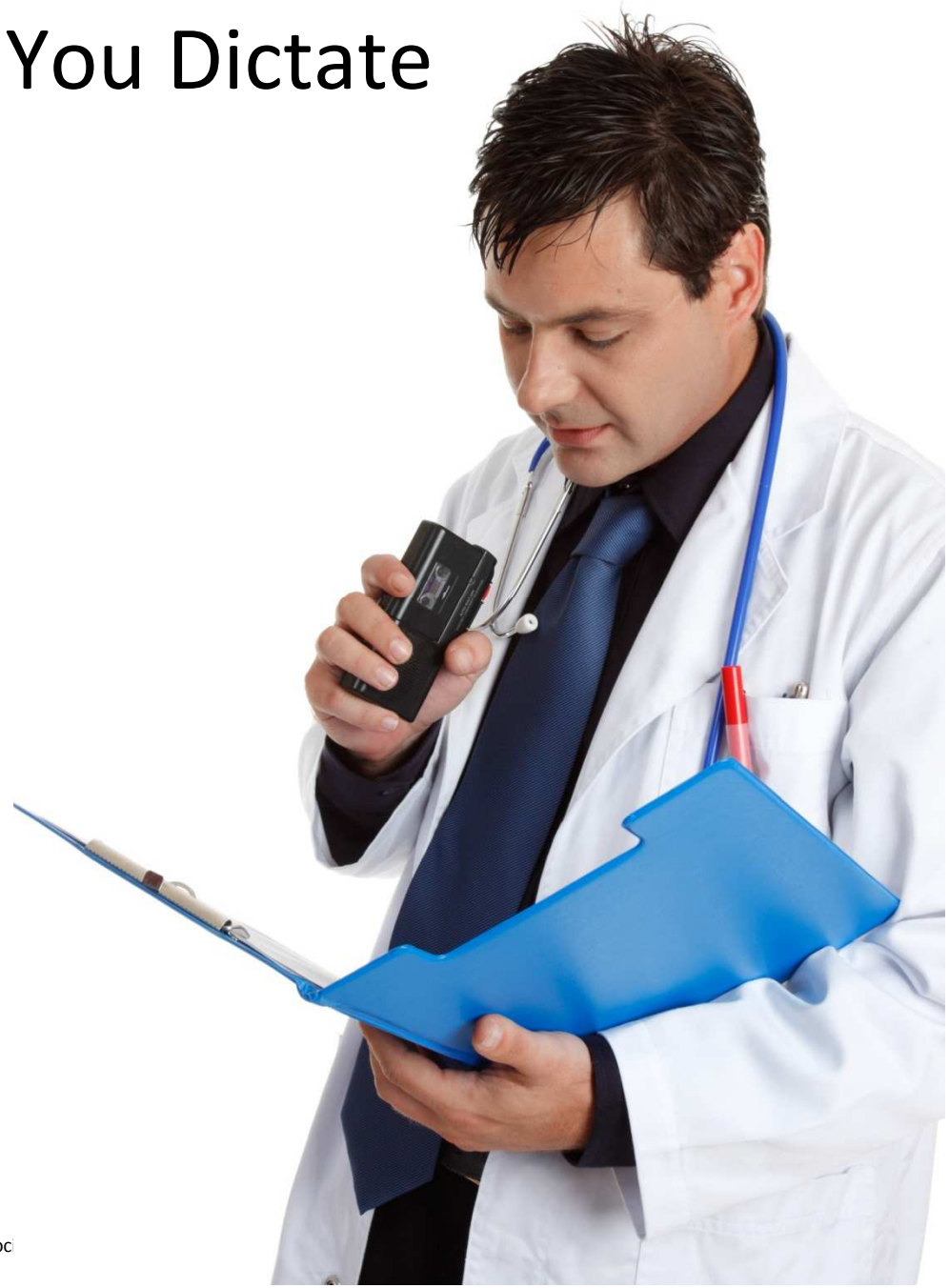
Mandatory second opinion in surgical pathology referral material: clinical consequences of major disagreements

- 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

Be Careful What You Dictate



Path Report:

- "10 lymph node fragments recovered **with none** showing metastatic deposits and the remainder showing only reactive changes"
- Should have said:

  "10 lymph node fragments recovered **with one** showing metastatic deposits and the remainder showing only reactive changes"

Wording your reports

"Diagnostic for metastatic squamous cell carcinoma"

Experts Would Have Reported :

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

Am J Surg Pathol 2012 Jan;36(1):e1-5

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 Jan;36(1):e1-5

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.

Reports consider

- 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 Jan;36(1):e1-5

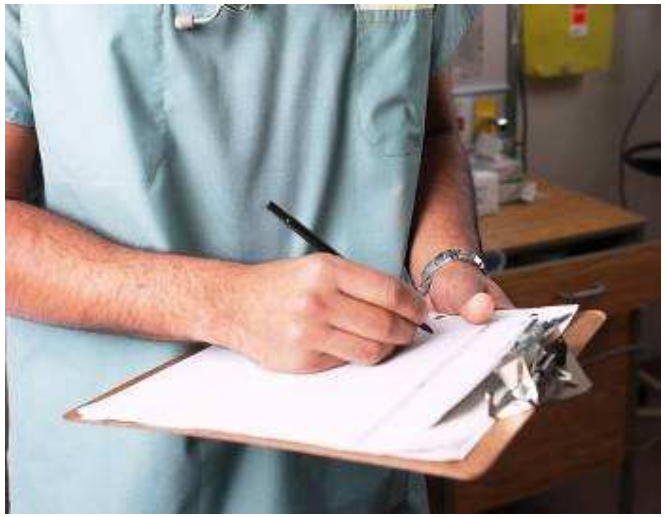
Reports consider

- 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 Jan;36(1):e1-5

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.

Legal Actions Pathologists:
Administrative Issues

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

Case #2

Legal Outcome

- CMPA settlement the plaintiff on behalf of Path and FP

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!

Risk management

- Are there clear policies and procedures: in 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?

What are the 3 things that can affect your defensibility as pathologist?

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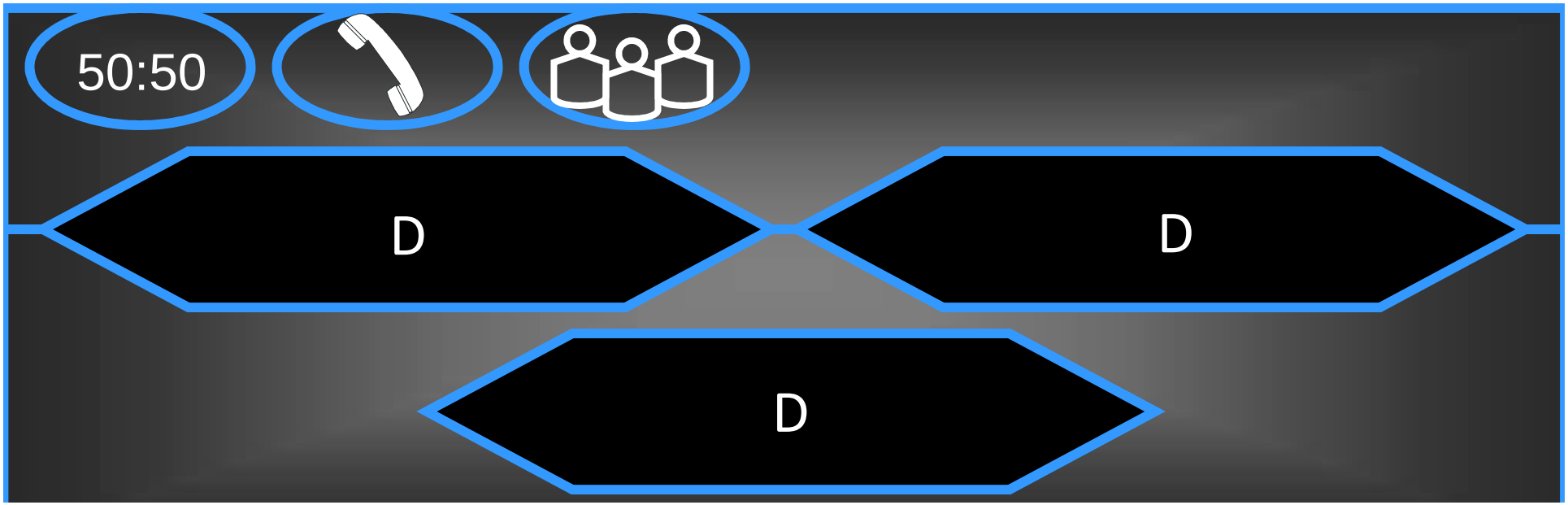

3 Ds that will affect your defensibility

- **D**elay in diagnosis
- **D**ocumentation
- **D**iligence with protocols

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
- Document your DDx, evidence for Dx , recommendations ,discussions with colleagues

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