Disclosure of Potential Conflict of Interest

• Relevant Relationships or COIs?
  – I sleep with Barry D. Kels MD, JD: UCONN Health Center’s Executive Director of Risk Management
  – Our son is health care lawyer: Sr. Counsel at AMA in Washington D.C.
DP Medical Legal Issues

1. Standard of Care / Expert Testimony
2. Not being definitive enough
3. Being too definitive
4. Comments on margins? Comments on Rx? Should we tell clinician what to do?
5. $ vs accuracy: Deeper sections, etc.
6. Dealing with lab externalities
7. Dealing with lab internalities
8. Dealing with errors
WHY is this Important?

- Lawsuits against pathologists increasing geometrically as public becomes more informed about role in medical care
  

- 13% malpractice claims $2^0$ to MM misDx
  
  *Sullivan. Skin Allergy News 2005; April:24-25*

- Pts know & like their derms. Pts often don’t sue folks they like. They never meet us!
BIOPSY PATHWAY

1. Identify Biopsy Site
   - Not representative of lesion
   - Not marked
2. Choose Biopsy Technique
   - Inadequate sample
3. Perform Biopsy
   - Wrong site
4. Place Specimen in Container
   - Specimen not in container
   - Container mislabeled
5. Combine Container with Requisition Form
   - Requisition form mislabeled
   - No clinical information submitted
6. Transport Specimen to Laboratory
   - Specimen left behind/lost
7. Gross/Process Specimen
   - Mislabeled specimens
   - Specimen not found in container
8. Pathologist Interprets Specimen
   - Lack clinical correlation
   - Multiple patient specimens mixed
9. Report Communicated to Physician
   - Physician not informed
   - Typographical error in report
10. Results Communicated to Patient
    - Patient not informed

Potential Errors

- Time out
- Mark site
- Write differential before biopsy, promoting technique choice
- Time out
- Multiple persons confirm label and specimen
- Multiple persons confirm fully complete requisition
- Log specimens
- Multiple persons confirm highlight small specimen
- Verify other identifiers (tissue size, shape, etc.)
- Specimen logs/reminders
- Review before signing
- Specimen logs/reminders

Medical Legal Implications

- **2 main causes for MM malpractice:**
  
  - 1) delay in dx
  - 2) mistaken dx (often 2⁰ to dermpath error)

- **Pre-analytic errors** due to quality of bx sample (size, crush, choice of bx site that does not adequately represent lesion, etc)

- **Analytic errors** = errors of interpretation

- **Post-analytic errors** = typos, misID of site or pt, failure to transmit report


*Crowson. Mod Pathol 2006;19:S148-154*
Errors in Pathology Dx

• 1 in 4 breast biopsies are initially misdx’d!  

• 5,011 MM pts path reports: dx change in 5.1% of cases after report on same specimen reviewed by specialist in MM pathology @ MM ctr

• Even when paths agreed on Dx, stage of cancer was changed in 22% of cases after reviews  
  Cochran. Should patients being considered for surgical management in melanoma ctrs have their histology reviewed by specialized pathologists? Ann Surg Oncol 2014; 21:2124-6
• Due to disagreements among paths & errors in > 10% cases: Panel of CAP experts & Assoc of Directors of Anat & Surg Path issued 2015 guidelines
  – protocol to review cases & resolve disagreements before results sent to referring MDs.
Diagnostic Errors

• Systematic review of 34 studies of malpractice claims from 5 countries
  – identified diagnostic errors & medication errors as most common types of preventable adverse events in ambulatory medicine

• Missed & delayed dx: particularly of cancer

Physician as Fiduciary

• Introduced by British physician-ethicists: John Gregory 1724-1773 & Thomas Percival 1740-1804

• 3 components:
  1. Commitment to scientific & clinical competence
  2. Commitment to the protection & promotion of the patient’s health related interests as the 1st concern & motivation, placing self interest as 2nd
  3. Commitment to medicine as a public trust, a social institution that should be strengthened & passed on to future physicians & their pts for the benefit of society

MEDICAL NEGLIGENCE

• Error ≠ Negligent malpractice
• MALPRACTICE = “negligence, misbehavior, neglect

– Medical Definition:
  Improper or negligent Rx of a pt … resulting in injury, damage, or loss; injurious or unprofessional Rx or culpable neglect of a pt

– Legal Definition:
  The negligent actions of a professional, such as a doctor or lawyer, as evinced by a failure to perform services consistent w/ the standards of such profession
Components: Duty, Breach, Causation, Damages

• **Duty** = Contract between pt (specimen) & dermatopathologist

• **Breach** = Error by omission or commission; failure to conform to relevant Standard Of Care (SOC) which is “proved” by expert testimony or by obvious errors (doctrine of res ipsa loquitur or the thing speaks for itself)
  
  – **Omission**: “failure to act” or Dx: ex. miss a MM
  
  – **Commission**: “negligent act”: ex. sign out MM as Spitz nevus
Components: Duty, Breach, Causation, Damages

- **Causation** = Harm caused by error. Breach of duty proximate cause of injury
- **Damages** = Harm
  Without damages (losses which may be pecuniary or emotional) there is no basis for a claim, regardless of whether the medical provider was negligent
- **Damages can occur w/o negligence** (ex, patient dies from MM)
1. Standard of Care (SOC) & Expert Testimony

- Act as a “reasonably prudent physician (w/ same qualifications) would act in same or similar circumstances” taking into account resources available (emergency, disaster) Annas. NEJM 2010; 362:2126

- W/ reasonable medical certainty would >50% of DPs or most trained DPs have made correct Dx?

- Dependent on expert opinion; consultant = expert

- Did lack of making the correct Dx or the way case signed out cause harm?
• Aug: Shave bx
• Dx: SCC
Sept: Excision
Feb: Pt told MM IV, @ least 2.6mm
March: Re-excision
Residual MM V 6.3mm & satellitosis; SLNB + CT lung & retroperitoneal Mets → death
Duty, Breach, Causation, Damages

- **Duty** – To make correct Dx in timely fashion
- **Breach** - Failure to make correct Dx (processing issues, no special stains done on initial bx); Failure to notify patient of correct Dx in timely fashion; → Delay in Rx
- **Causation** - Delay in timely notifying pt of correct Dx
- **Damages** – Metastatic disease & death
- **NEGLIGENT**
- **or DEFENDANT’S VERDICT**
- “… more likely than not that failure to timely Dx MM … was a contributing factor in pt's demise. …chance of survival was diminished”
Standard of Care (SOC)

• W/ reasonable medical certainty >50% of Derms/DPs or most trained Derms/DPs would have made correct Dx & notified the patient in a timely manner

• The correct dx should have been made & the lack of making that Dx or the way the report was signed out & patient informed played a role in the harm & loss of chance
Did the action of the dermatopathologist culminate in negligence?

- Breach that causes harm
  - Driving drunk is negligent $\rightarrow$ no accident, no harm
  - Driving drunk & hit car $\rightarrow$ proximally caused harm

- Improper dx or handling of a specimen that results directly in harm to patient
Expert Testimony

- **Expert Witness** has “sufficient knowledge, education, training, or experience” regarding specific issue before the court.

- **Qualifications of expert:**
  
  Expert testimony is not qualified "just because somebody w/ a diploma says it is so"

Proposed Expert Testimony Must Meet Criteria For Reliability

- **Gatekeeper (Dauber) Standard**: Before federal trial & in > ½ the states, hearing before judge (w/o jury) considers evidence to determine whether expert's "testimony rests on reliable foundation & is relevant to task @ hand"  
  *Daubert v. Merrell Dow Pharmaceuticals* 1997

  - **Flaw** → Opinion of a single judge

- Trial by jury of your peers?
2. Not being definitive enough?

- “Bowenoid AK, focal Bowens cannot be ruled out”
- Some derms will assume AK → cryo it. If recurs as SCC clinician may blame you!
- Others will Rx as Bowens → lesion on tip of nose → referred for Mohs
- Mohs surgeon gets investigated for doing Mohs on an AK (as was coded on path billing sheet)
- Will this derm & Mohs continue to send you cases?
- Say what you mean & mean what you say!
3. Being too definitive?

• AMH on sun damaged skin → sign out MMIS
• Facial lesion → Slow Mohs.
  Lesion extensive → large scar & expensive
• Mohs surgeon investigated for over treating (over charging) (unnecessary Mohs?)
• Will they continue to send to your lab?
• **Say what you mean & mean what you say!**
Equivocal Dx?

- Most MDs have sense of obvious Vs equivocal Dx
- Consultants should give another dermpath leeway re: equivocal dx. Can we appreciate how Dx missed?
- W/ reasonable medical certainty we should excuse equivocal or obscure Dx
- Legal standard of reasonable medical certainty = > 50% of DP practitioners would have made this Dx or signed out the case in similar manner
Known Unknown

• “There are **known knowns**. These are things we know that we know. There are **known unknowns**. That is to say, there are things that we now know we don’t know.

• But there are also **unknown unknowns**. These are things we do not know we don’t know.”

*Donald Rumsfeld  Feb 12, 2002*

• **Ambiguous, borderline lesions** = **known unknowns** ≠ **malpractice**

*Scolyer, et al. Arch Pathol Lab Med 2010;134:1770*
4. Comments on margins? Comments on Rx? Should we tell clinicians what to do?
DP sued b/c did not mention margins +
Duty, Breach, Causation, Damages

- **Duty** – Correct Dx made (clinical dx: seb K)
- **Breach** - Failure to comment on margins of scoop shave bx
- **Causation** - Lack of reporting margins caused the lesion to metastasize?
- **Damages** – Lesion metastasized
- NEGLIGENT or
- **DEFENDANT’S VERDICT**
- Famous DP testified against defendant!
Hippocrates

“Whenever a doctor (or expert witness) cannot do good, he must be kept from doing harm.”
5. $ vs accuracy: The “Deeper” Conundrum

• 1/1/2013 CMS reduced payment for 88305 by 33%.
• Will DP labs deepen on specimens? = work but no $.
• Prospective review: 200+ cases over 105 day period
  – Dx after review of 1st section
  – Dx after review of 3 prospective deeper sections
  – Compare Dx’s: If change in Dx did it alter clinical Rx?
• Expenses were analyzed for 3 diff scenarios:
  1) bx w/ no additional sections (least expensive)
  2) bx w/ prospective deepers
  3) bx w/ retrospective deepers (most expensive)

• Deeper sections thru block enhanced dx’ ic accuracy:
  – 9% (18/204) of prospectively multiply sectioned specimens resulted in dx change
  – In 56% of these cases, this change in dx (overall 5% of cases) resulted in alteration of clinical Rx

• To avoid delays & to enhance dx’ ic accuracy while minimizing expenditures, prospective deeper sections recommended

6. Dealing with Lab Externalities: Courier Car Accident

- Courier vehicle that transports specimen bottles from various referring doctors’ offices skidded off the highway on “black ice” → severe collision
- Collision resulted in dispersal of numerous specimen bottles over a mile or more of interstate highway

7. Dealing with Lab Internalities: Lost Specimen

• Receive specimen bottle w/o specimen
  – Filter formalin, inspect cap & sides of bottle → notify clinician & document

• Specimen tiny, received in fragments → Dissolves during processing

• Poorly oriented, cut or stained sections…

8. Deal With Errors: NOTIFY & Issue Revised Report

- Immed notify clinician → explain & plan how to let patient know; offer to discuss w/ patient
- Why paths do not tend to disclose errors to patients:
  - Increases sense of culpability & damages
  - Harms relationship w/ referring clinician
  - Pathologists don’t usually talk to patients – “unprecedented” / “impractical”
  - Clinicians communicate w/ patients
  - Pathologist has no relationship w/ patient

Harms Relationship With Referring Clinician?

- Dual/conflicting fidelity of pathologists
- To whom is pathologist most faithful: Derm or Pt?
  - CAP mission statement: The CAP serves *patients*
  - ASDP mission & vision: Improve quality of lives [&] reduce burden of skin disease
  - ACGME pathology training: Needs of *patient* first
  - AAD core values: *Patients* first

CLINICIAN  PATIENT

Drawn by Ben Stoff
What does it mean to put patients 1st?

- Duty to be truthful  

No relationship with patient?

- “Courts have thoroughly established that pathologists have a clear doctor-patient relationship… A pathologist is neither more or less of a consultant than any other clinical physician.”  

- Fiduciary relationship based upon:
  - Trust (AMA opinion 10.015)
  - Expectation of competency
  - Payment
Appeal to Non-Moral Reasoning: Self Interest

- Potentially culpable party to represent error to pt?
- Conflict of interest

Courtesy of Ben Stoff, MD
Trial in Philadelphia
Trial in Philadelphia

Experts for:

- plaintiff: 98% chance of cure
  - 85.6% eight-year survival
  - good for cure

- defense: zero chance for cure
  - practical non for survival
Duty, Breach, Causation, Damages

- **DUTY**: To look at all sections of the tissue
- **BREACH**: Failure to look at all sections
- **CAUSATION**: Breach → failure of Dx of MM
- **DAMAGES**: Pt died; Loss of chance
- “If you find that injuries, damages, or losses were in fact sustained & caused by the lost chance of survival & Defendant’s negligence then you may award damages resulting from Plaintiff’s lost chance of survival.”
- **NEGLIGENT**
- or **DEFENDANT’S VERDICT?**
59 yo male with back lesion
Signed out by derm as DFSP. Not excised for months. Never widely excised

Lung and lymph node mets → Death

DUTY: To make correct Dx & timely Rx

BREACH: Failure to timely Dx & Rx

CAUSATION: Breach → failure of Dx of MM

DAMAGES: Pt died; Loss of chance

NEGLIENT

or DEFENDANT’S VERDICT?
Loss of Chance State

• If Defendant was negligent → did negligence cause Plaintiff to lose sig chance of detecting & Rx’ing MM & surviving or extending survival

• “Should you find by a preponderance of the evidence that the Defendant’s act(s) or omission(s), if any, to a reasonable degree of medical probability caused a loss of chance or opportunity to Plaintiff, you may base your verdict on that lost chance or opportunity, whether a possibility (less than 50%) or a probability (greater than 50%)”
IF YOU MADE A MISTAKE …

• Cut your losses & move on to the next slide and your life!
We are Capt of the Ship & Responsible for Specialists We Refer to & Ourselves

• Shave Bx: fragments of hyperplastic AK, margins +
• Pt scheduled for excision → lesion tripled in size
• Referred to plastic surgeon same day for excision
• Plastic surgeon independently decided this was a KA & decided to see if it would spont regress
• 6 months later lesion excised → SCC extended into fat & intravascular → mets & death
• Plastic surgeon settled
• Derm went to court & lost. Got divorced. Died.
• Whether we are defendants, plaintiffs, or expert witnesses we need to behave with “integrity, dignity, civility,” & empathy.

• Thank you for your attention!
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