Medical-Legal Issues with Electronic Health Records

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Conflicts

- I have served as an expert witness for both plaintiff and defendant malpractice cases
- I have used EMR's
- My wife is a lawyer…

Objectives

- Define malpractice
- Review the frequency of malpractice litigation
- Discuss the design of EMR software
- Review common EMR problems that increase the risk of malpractice litigation
  - Automated vital signs/lab results
  - Outside documents
  - Documentation conflicts
  - Electronic order sets

Definition of Malpractice

- Did the provider do what another provider would do in same or similar circumstances?
- If there is a standard of care which applies to the clinical situation, did the provider meet the standard of care?
- If the provider did not meet the standard of care, does the preponderance of the evidence suggest that the breach in the standard of care resulted in the patient injury?
- Malpractice requires a breach in the standard of care which is directly or indirectly related to the injury of the patient

Examples of Malpractice

- Not following the AWHONN/ACOG/CDC guidelines for Group B Strep prophylaxis
- Fundal pressure that contributes to a shoulder dystocia
- Failure to notify a provider of abnormal vital signs such as severe HTN
- Medication errors that results in patient injury

Malpractice in Georgia

- ACOG- 80% of all practicing OB/Gyn physicians will be served a notice of malpractice litigation listing them as a defendant
- Fewer than 1% of nurses will be served a notice of malpractice litigation
- Common for OB/Gyn physicians to have settled 1-2 cases during their career
- 80% of malpractice cases that are filed result in an award to the defendant patient

Deep Pockets

- Institutions such as hospitals are more likely to actually pay out large cash awards to patients.
  - Example
  - Nurse Nikia is named in a malpractice suit. She does not have an individual malpractice policy. Nikia owns her home but has a mortgage. Her checking and savings accounts have less than $2000. Her car is paid off but is 8 years old.
  - Nikia's employer is a regional hospital corporation that owns several hospitals in the metro Atlanta area. The total income for the regional corporation is over $ 1 billion

Deep Pockets

- Nikia's net worth is modest. Even if the jury ruled against her in a $ 1 million malpractice case, the plaintiff would only get a few thousand dollars before Nikia declared bankruptcy.
- Nikia's employer has a sophisticated malpractice protection system with Georgia insurance and reinsurance with an international carrier. Nikia's employer has set aside funds every year in reserve for malpractice payments based on past history and current climate.
- The plaintiff is much more likely to get substantial award payments from Nikia's employer than from Nikia

Shallow Pockets

- The plaintiff's attorneys are less interested in Nikia losing her lawsuit that they are in getting information from Nikia that can be used to pressure her employer into a settlement.
- Typically, Nikia's attorney is the same as her employer's attorney, even though there is a conflict of interest.
- Nikia's employer wants to minimize the potential financial impact of a settlement.

General Guidelines

- Review the chart and your involvement in the case before your give testimony.
- Only relate the facts. Don't assume anything. Only discuss your involvement.
- Tell the truth! It's against the law to lie under oath.
- Keep answers short. Don't volunteer extra information.
- Stop taking when your lawyer objects.

Malpractice in Georgia

- Malpractice cases are over-represented in inpatient care (worst outcomes)
- OB/Gyn physicians are more likely to be accused of ***not doing the right thing*** than doing the wrong thing
- (failure to …)
- Delay in performing a cesarean section is the most common allegation

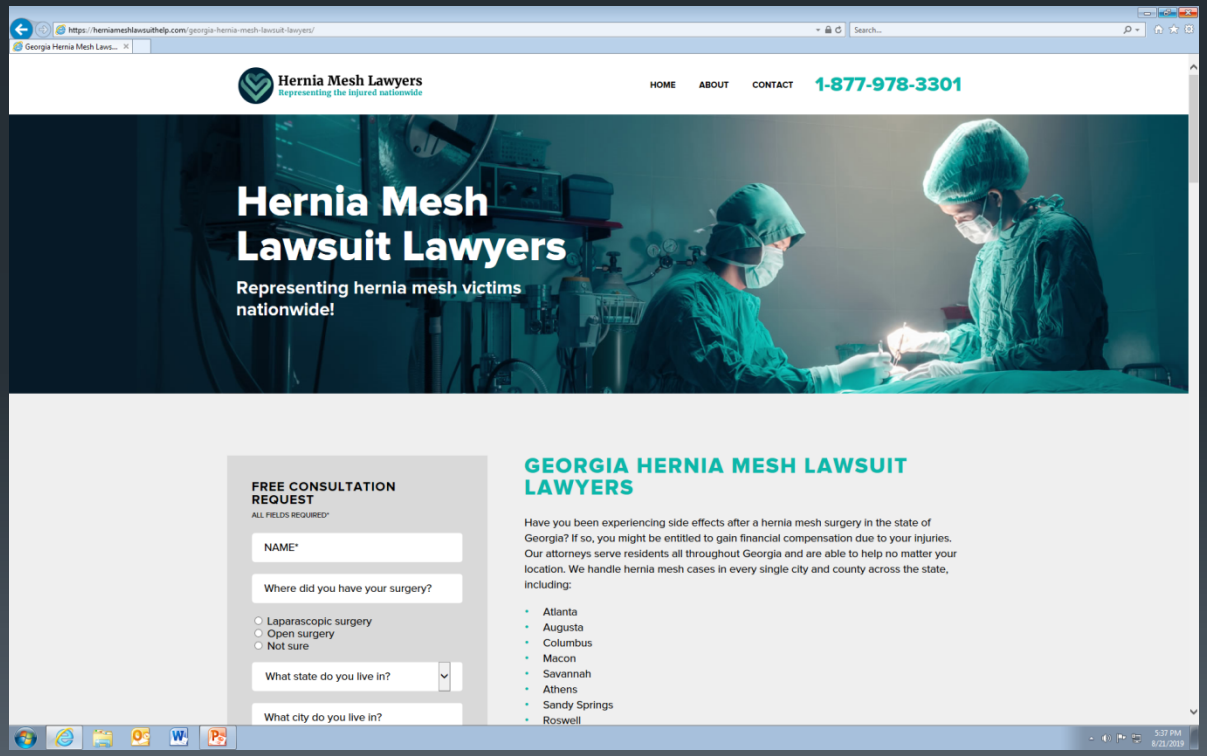
Malpractice in Georgia

- Patients seek attorneys for several common reasons:
  - Unexpected bad outcome
  - Death of a patient or newborn
  - Permanent injury related to surgery

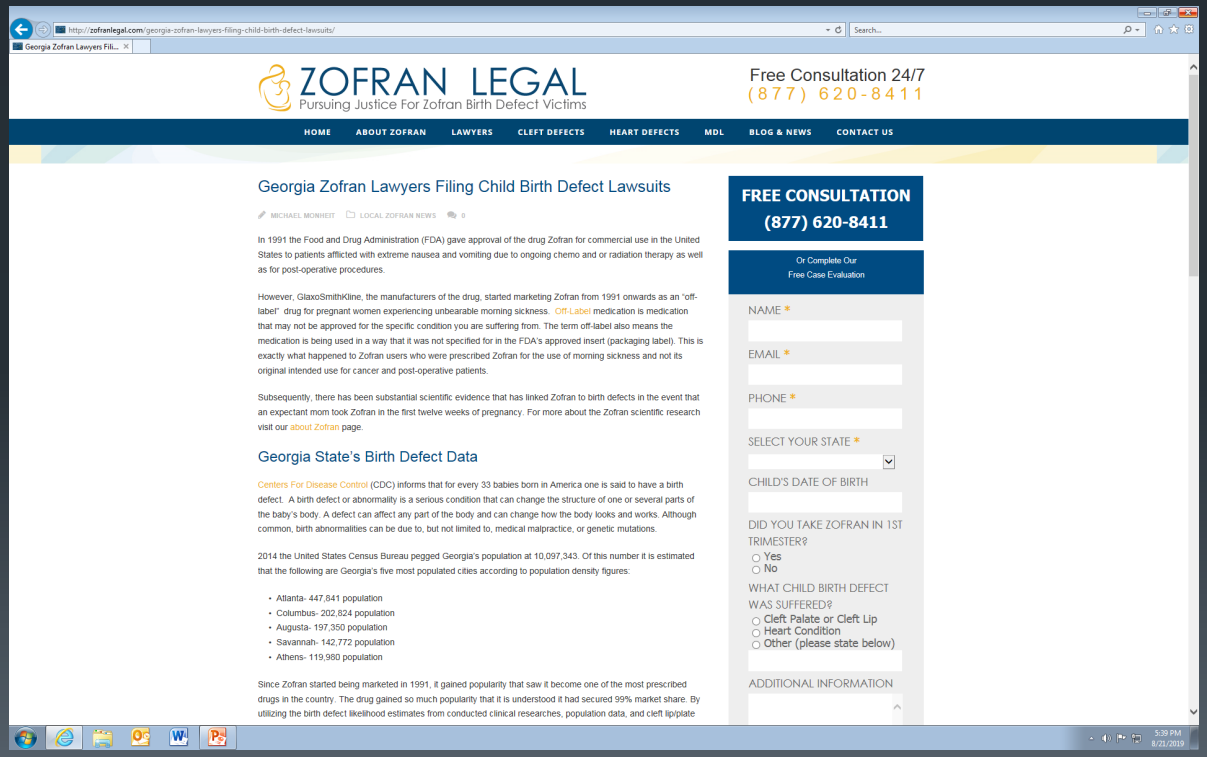
Malpractice in Georgia

- The Georgia Bar discourages attorneys from directly advertising for clients (“ambulance chasers”)
- Attorneys use media to find new clients
  - Class action lawsuits
  - Sentinel cases against drug manufacturers
  - Sentinel cases against device manufacturers
  - FDA actions against a manufacturer

Malpractice in Georgia

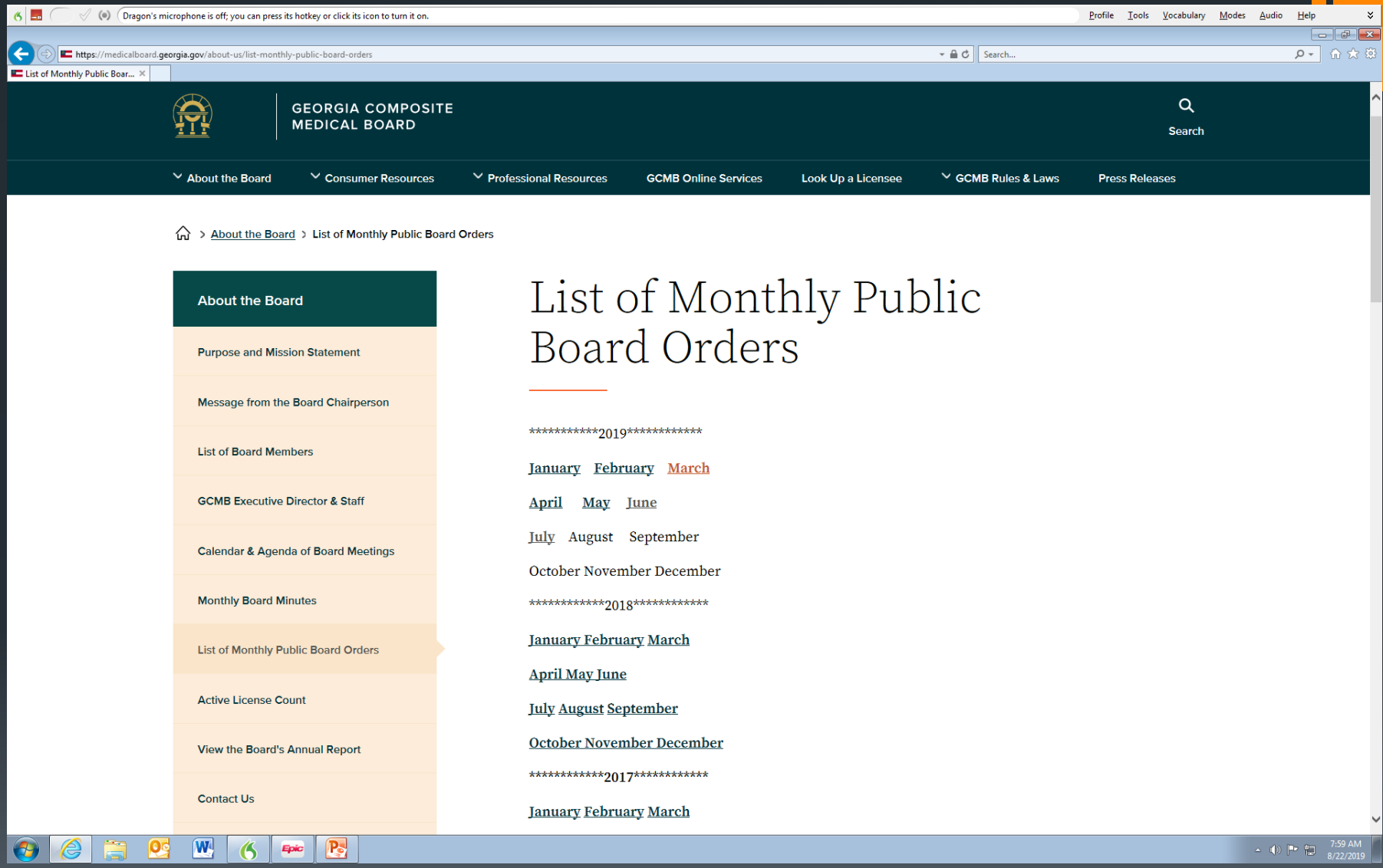


Malpractice in Georgia



Malpractice in Georgia

- Are providers always innocent?
- No! There are bad providers in Georgia.
- Most healthcare workers require a state license to practice.
- Georgia Composite Medical Board issues dozens actions against Georgia providers every year which range from DUI school to permanent loss of their license to practice medicine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**********2019**********
January February March
April May June
July August September
October November December
**********2018**********
January February March
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October November December
**********2017**********
January February March
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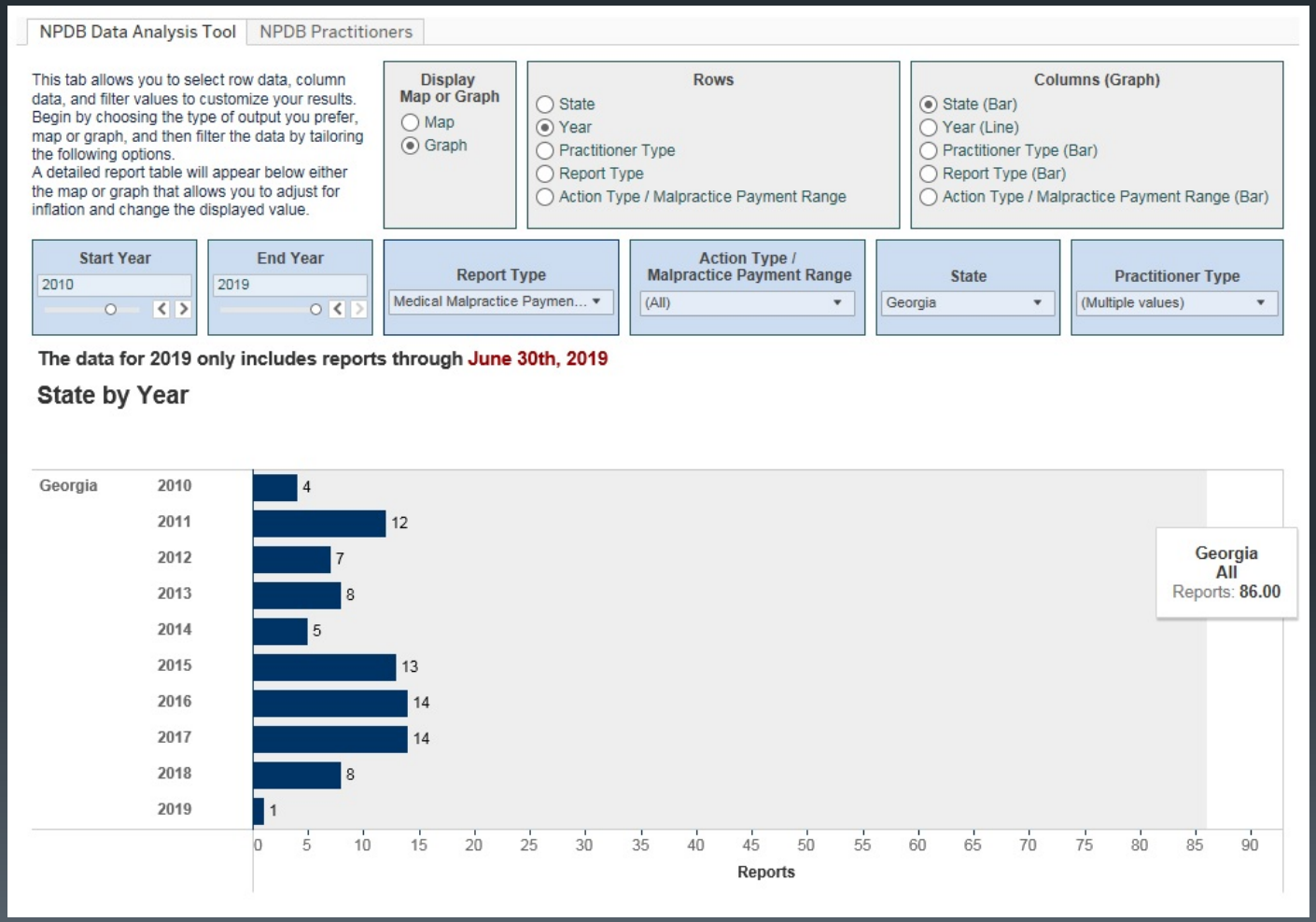
Malpractice Payments in Georgia

Report Detail Table

		State: Georgia	Total
Year	2010	204	204
	2011	205	205
	2012	185	185
	2013	220	220
	2014	222	222
	2015	225	225
	2016	213	213
	2017	233	233
	2018	288	288
	2019	130	130
	Total	2,125	2,125

Courtesy National Practitioner Data Bank

Malpractice Payments in Georgia for Nurses



Courtesy National Practitioner Databank

Malpractice Insurance

- Three Types
  - Occurrence
    - Pay a premium for a year and any malpractice case arising from care during that year is covered even if it is filed years later
  - Claims Made
    - Pay a premium for a year and any malpractice case filed during that year is covered
  - Tail Coverage
    - Pay a premium when you leave the state or retire to cover any future litigation claims

Ask you to switch places…

- Your mother is admitted for a hysterectomy
- You referred her to a Gyn you know
- During her laparoscopy-assisted hysterectomy, she has a undiagnosed bowel perforation.
- She goes home, and later gets readmitted with a fever and abdominal pain.
- She is treated for infection with IV antibiotics. She becomes septic and requires Rapid Response for hypotension.
- She is take to the OR and needs a colostomy. She loses 15 cm of small bowel and develops short gut syndrome.
- She suffers some CNS injury and now has very poor short-term memory at age 50.

Now you are the Plaintiff's family

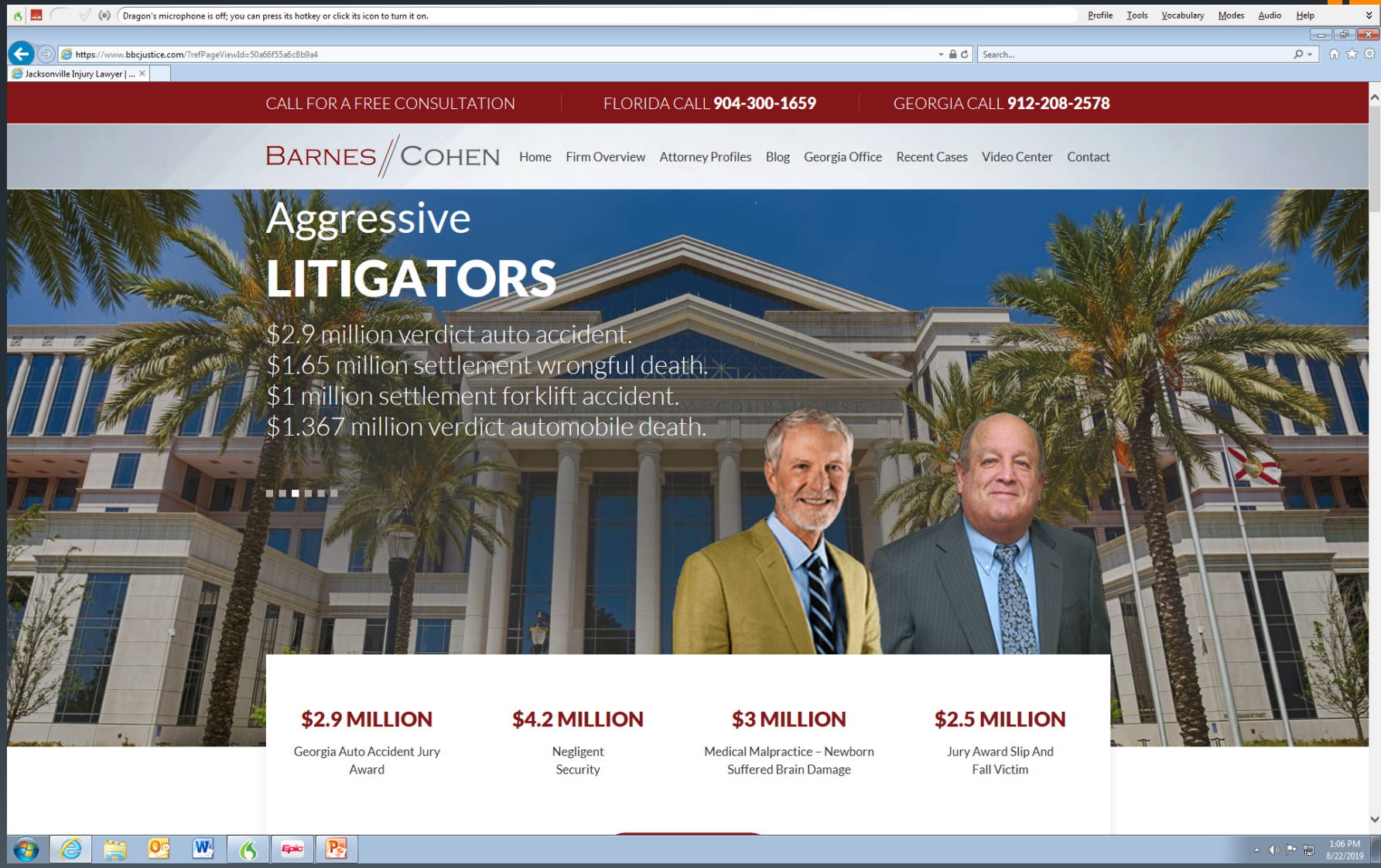
- You find out this is not the first time a bowel perforation has occurred during a laparoscopic hysterectomy performed by this provider
- No imaging was performed prior to your mother's Rapid Response assessment. This might have allowed an earlier intervention.
- The on-call Gyn saw your mother the morning of the colostomy and said she was "fine". You were there and do not recall the provider performing a physical exam. She just came in and spoke to your mother and you.

Malpractice- The Process

- The patient believes the care received was sub-standard
- The patient consults an attorney and explains the case
- The attorney makes a decision whether to accept the patient as a client
- The attorney begins a process called “discovery” where medical records are reviewed and expert witnesses are asked to give an opinion

Malpractice-The Process

- In Georgia, a malpractice litigation cannot be filed unless a physician licensed in Georgia provides a sworn affidavit that malpractice has occurred
- The malpractice allegation is filed in court.
- The court sends you a “summons” giving you notice that you are named as a defendant in a malpractice case
- Typical time frame- 2 years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$2.9 million verdict auto accident.
$1.65 million settlement wrongful death.
$1 million settlement forklift accident.
$1.367 million verdict automobile death.
$2.9 MILLION
Georgia Auto Accident Jury Award
$4.2 MILLION
Negligent Security
$3 MILLION
Medical Malpractice – Newborn Suffered Brain Damage
$2.5 MILLION
Jury Award Slip And Fall Victim
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Electronic Medical Records

- Started with application software for medicine in the 90's
- Every part of medicine had separate licensed software
  - Word processor
  - Billing and Collections
  - Radiology reporting
  - Lab ordering and displays
- Early EMR's tried to put all those functions together
- Rather than M&A, each company tried to invent a "better mousetrap"


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Electronic Medical Records

- So, what software had priority?
  - (go where the money is…)
  - Billing and Collections!
- Every part of an EMR is designed to make sure you can automate billing of that clinical activity
- The patient care portion of the EMR was not a priority until this decade
- The provider burden for documentation increased dramatically in the last 20 years
- Documentation in the EMR is the #1 complaint of providers

Who codes EMR's?

- Not doctors
- Not nurses
- EMR's have focused on "data analytics" not "visual analytics"
- The priority of that the code works, not that it mimics workflow or is easy to enter data
- EMR's encourage standardization, but not necessarily good health care

EMR Work-arounds

- Who has had to find a “work-around” for poor functionality in an EMR?
- All of us!
- Highlights the difference between “data analytics” and “visual analytics”
- “Data analytics” means the programmer got the right answer.
- “Visual analytics” means the programmer got the right answer and integrated the data into the EMR in a manner that matches work flow

EMR features that increase litigation risk

- Review common EMR problems that increase the risk of litigation
  - Automated vital signs/lab results
  - Outside documents
  - Documentation conflicts
  - Electronic order sets

Automated Vital Signs

- Ms. Jones is a 28 year old female at 35 weeks being assessed in Triage for headache. Her BP with the automated cuff is 180/120. You readjust the cuff. All the rest of her BP readings are normal. Her UA is negative for protein.
- After 2 hours of observation, Ms. Jones is sent home.
- She returns 4 days later with pre-eclampsia and an IUFD. She is admitted and induced.
- She sues claiming that the provider should have admitted her for evaluation of acute hypertension after the first encounter.

Automated Vital Signs

- Basis for the lawsuit is a single elevated BP
- Was that BP valid or did it represent an automated vital sign error?
- The BP reading is in the EMR record because it is automated.
- The BP reading cannot be removed from the EMR.
- Should this patient have been admitted for her one-time BP of 180/120?

Automated Labs

- Ms. Smith is a postpartum patient who had a cesarean section for arrest of descent. Her postpartum Hg is 6.2 gm%. She is asymptomatic with normal vital signs. The provider orders 2 units of PRBC's to be transfused.
- Her post-transfusion Hg is 12 gm%. The patient has a transfusion reaction which results in acute renal failure and dialysis. The patient has persistent chronic renal failure.
- She sues claiming that the Hg of 6.2 gm% was not accurate and that she should not have been transfused.

Automated Labs

- Was the lab result accurate?
- Typical causes of low Hct lab result
  - Patient anemia
  - Drawing from IV port instead of venipuncture
  - Too little volume in the sample tube
- Should it have been repeated?
- If the repeat was different, which one was the accurate result?

Outside Documents

- Ms. Perez re-located to be with family at the time of her delivery. She is 39 weeks and in labor. She reports her OB doctor told her that her fetus had Trisomy 18. She declined an amnio. Ultrasound in Triage shows an AGA fetus with normal amniotic fluid volume in a cephalic presentation.
- Ms. Perez requests aggressive management including intubation. The neonatologist argues the intervention is unethical based on the prenatal diagnosis of Trisomy 18. He advises her to transfer to another facility.
- The patient sues under the Americans with Disabilities Act (ADA) claiming her disabled child was denied treatment.

Outside Documents

- How accurate is the diagnosis of Trisomy 18?
- The patient did not have a diagnostic test.
- Risk screening tests have varying accuracy.
- Was the patient counseled about false-positive results?
- Was the patient counseled about true positive results?
- Should you offer a cesarean section for non-reassuring tracing in a fetus who might have Trisomy 18?
- Should the fetus be intubated and given CPR if it decompensates in the delivery room?

Documentation Conflicts

- Ms. Brown has a shoulder dystocia of an 8 lbs infant. The infant has Erb's palsy. The physician documents McRobert's manuver and fundal pressure. The nurse documents suprapubic pressure.
- Two years later, both are giving depositions. The lawyer implies that the nurse is lying about suprapubic pressure to cover the doctor. The nurse insists she did not give fundal pressure.
- The lawsuit is settled before trial.
- What happened?

Electronic Order Sets

- The providers at your hospital approved an order set for antibiotics to be given to patients with increased risk of Group B Strep infection. The order set was approved in 2015 and re-approved every 2 years. The CDC has just changed their guidelines.
- Ms. Wu is Group B Strep negative. She should get IV antibiotics based on the old guidelines and should not get them based on the new guidelines. The order set is executed. The patient has anaphylaxis from her IV penicillin.
- Her family sues stating she should not have been given Pcn based on the latest CDC guidelines.

Automated Vital Signs

- Medical-Legal Risk
  - All patient data is equally deserving.
  - No data is removed from the EMR
  - Rogue vital sign data is just as valid as other data
  - In a lawsuit where having an abnormal vital sign which did not prompt intervention is an issue, the Rogue vital sign becomes the real data and the other vital signs are discounted

Automated Vital Signs

- What's the solution?
  - Create a procedure where an outlier vital sign is objectively shown to be inaccurate:
    - Repeat the vital sign a number of times
    - Trend the vital sign over the hospital course
    - Allow a comment to be added to the vital sign data from the provider indicating that the provider's medical opinion is that the vital sign is not accurate
  - Have a policy where an outlier vital sign's potential adverse consequence requires additional monitoring

Automated Vital Signs

- Back to our example:
  - Ms. Jones' BP 180/120
- Policy would state to repeat the BP every 5 minutes over the next 30 minutes
- A graph of the patient's BP over the day would clearly show it to be an outlier
- PIH labs would be drawn as part of the policy to ensure the patient does not have early pre-eclampsia
- A note would be added next to the BP after completing the protocol stating that it appears to be an inaccurate reading

Automated Lab Results

- Ms. Smith's Hg of 6.2 gm%
- Policy for transfusion would state the low Hct must be repeated in a stable patient
- Policy for transfusion would state that PRBC's would only be released if two sequential Hg measurements were abnormal
- Postpartum hemorrhage protocol could be amended to address hemodynamically stable anemia following delivery
- If the subsequent Hg is significantly higher, an automatic Quality report would be required to address lab inaccuracies

Outside Documents

- The presence or absence of outside documents is critical to ensuring good patient care.
- If outside documents are not available, EMR records should not assume the accuracy of patient statements:
  - “The baby has Trisomy 18”
  - “The patient reports she was informed that her NIPS showed an increased risk of Trisomy 18”
- Efforts to obtain outside medical records should be documented in the EMR
- In the absence of confirmatory medical records, take the most conservative approach.

CPOE/Electronic Order Sets

- Ms. Wu's antibiotics for Group B Strep
- Updating CPOE must be a rapid progress (2 weeks or less). Implementing new guidelines soon after they are published should be a priority for hospital administration.
- The source of the information (AWHONN/CDC/ACOG) should be considered. Peer-review publications and UpToDate recommendations should be vetted by national organizations before being incorporated into CPOE.
- Changes in CPOE sets should be broadcast to all providers prior to their implementation to avoid confusion and reversion to old order sets.

How do we prevent malpractice?

- Proactive methods
  - Educate your staff on the current standard of care.
  - Update you policies to reflect the current standard of care.
  - Create an expedited process for updating policies to reflect changes in the standard of care.
  - Always publicize updates in policies or CPOE to all stakeholders well in advance of implementation.
  - Standardize informed consent for procedures, so patients have a more realistic idea of potential complications

How do we prevent malpractice

- Retroactive
  - Facilitate incident reports for breaches in the standard of care:
    - Failure to report abnormal vital signs
    - Medication errors
    - Non-reassuring FHJR tracings
    - Patient dissatisfaction
  - Empower nursing to directly address breaches in the standard of care or unexpected bad outcomes with patients.
  - Adhere to a strict policy of staff education and remediation for incident reports
  - Terminate staff who fail to improve performance

Georgia consent forms

- Language mandated by the legislature so patients are aware of potential serious complications and death.
- Latest example is the requirement to request informed consent for pelvic examination under anesthesia by learners such as nurse practitioners, CNM students, PA students, medical students, residents, etc.
- Providers are unlikely to discuss rare events such as brain injury or death that can occur after common procedures such as cesarean section, vaginal delivery or hysterectomy

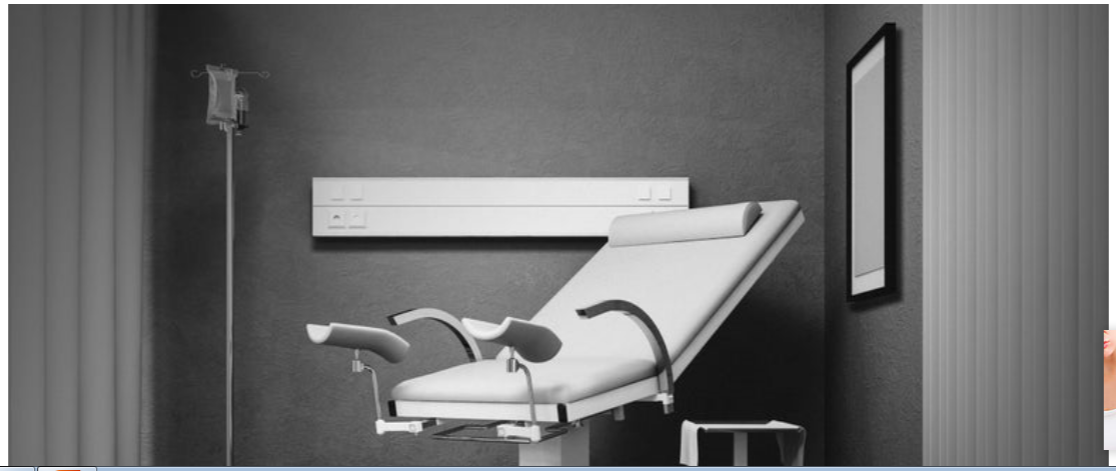
"Material risk" means a material risk generally recognized and accepted by reasonably prudent physicians of infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadraplegia, disfiguring scar, brain damage, cardiac arrest, or death which could result from the major surgical or diagnostic procedure and which, ***if disclosed to a reasonably prudent person in the patient's position, could reasonably be expected to cause such prudent person to decline the major surgical or diagnostic procedure*** on the basis of material risk of injury that could result from the major surgical or diagnostic procedure.

Why Are Pelvic Exams on Unconscious, Unconsenting Women Still Part of Medical Training?

We understand consent better than ever. So why haven't we ended this practice?

By PHOEBE FRIESEN

OCT 30, 2018 • 9:00 AM



News

Home

Wilson: #MeToo? Some Hospitals Allow Pelvic Exams Without Explicit Consent

JAN 17, 2019 2:00 PM

FACULTY FEATURED

A law professor in Illinois wants to put a stop to a medical practice that she says treats women's bodies like cadavers.

Across most of the U.S., teaching hospitals allow medical students to conduct pelvic exams on female patients without their knowledge or explicit consent.

Some medical schools say these exams are standard practice and necessary to teach students. And the practice remains legal in all but six states, including Illinois and Iowa.

But Robin Fretwell Wilson of the University of Illinois at Urbana-Champaign says women should have a say on the issue. She hopes to draw attention to it in the wake of the #MeToo movement.

Side Effects Public Media spoke with Wilson about her recent *Chicago Tribune* editorial, calling on medical associations to help end the practice.

Side Effects: I imagine a lot of women would be disturbed to learn they may have been subject to a pelvic exam without their knowledge or consent. How common is this practice?

Robin Fretwell Wilson: Well, we actually don't have terrific data. What we have are accounts from medical students who say, "I'm disturbed, why aren't we having a conversation about this, in terms of medical ethics?" We have residents saying that it was a normal teaching practice. So, we know the practice happens as a teaching matter. We know that often it's not consented

Avoiding malpractice when using an EMR

- Follow employer policy. Violating employer policy increases the risk of malpractice allegation.
- Document well. Even when you are tired or late leaving, you never know if that documentation will be the one used to create an allegation of malpractice.
- Adopt the TeamSteps approach if you disagree with patient care. “I feel uncomfortable…”
- Prioritize your relationship with the patient. Patients are less likely to sue providers whom they like.

Avoiding malpractice when using the EMR

- Stay current. Conferences like this help you to bring back new ideas and emerging care to your locality.
- Insist that changes in the AWHONN policy be incorporated into your local EMR ASAP.
- Don’t be scared if you are asked to give a deposition. They are not after you. They are after your employer.