

Share the Vision of Healthcare Risk Management through the "Eye of the Commonwealth"

# Informed Consent and Medical Liability

Not a Matter of Form



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## Disclaimers

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## Presenters

- Chad Brouillard, MA JD, Foster and Eldridge, LLP
- Jim Purcell, Taylor Healthcare
- Glen Gilman, Taylor Healthcare

• *Please refer to the Presenters' Bios available on the table for more information*



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## Informed Consent

- Ethical obligation
- Professional obligation
- Legal obligation
- Potential for liability and risk
- Accreditation



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## Informed Consent- Benefits

- Patient centered care
- Increased patient-physician communication
- More realistic expectations
- Helps close the loops with follow up
- Increased patient satisfaction
- Fewer medical malpractice claims



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## Joint Commission Study (2016)

- 44 sentinel events directly related to informed consent
- 32 related to wrong site wrong surgery
- Remainder related to operative or post-operative complications, elopement, falls, medication errors and suicide



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## Informed Consent

- What is consent?
- What defines it? Laws, guidelines, policies
- What is the legal effect of an informed consent form?
- Who provides consent?
- Exceptions to consent?



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## Informed Consent- Legal Requirements

- State-Based laws (50+2 different ones)  
*For instance, telehealth, opioids, duty to warn*
- Professional licensure obligation
- Laws
- Practice specialty requirements



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## Informed Consent- Example

Massachusetts General Laws, Chapter 111, § 70E: medical patients have the right "to informed consent to the extent provided by law."

- No mention what "extent" means in any given context
- No direction as to what types of procedures need consent
- Relies on case law



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**Informed Consent –  
MA Board of Medicine Regulations**

243 CMR 2.07 (26):

A physician has the obligation to obtain and record a patient’s written informed consent before diagnostic, therapeutic or invasive procedures, medical interventions or treatments. Informed consent means that the physician has disclosed and explained to the patient’s satisfaction the process used to arrive at the medically reasonable and recommended procedure, intervention or treatment, based on reliable evidence of the expected benefit and risk of each alternative, free from any impermissible bias.



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**Informed Consent –  
MA Board of Medicine Regulations**

243 CMR 2.07 (26):

- Consent must be in writing
- Written policy (who obtains, how)
- Non-delegable duty of primary physician/surgeon
- Clear and detailed standard
- Must document who will be present/absent



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**Informed Consent- Definition**

Permission granted in the knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with full knowledge of the possible risks and benefits.



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### Informed Consent- Historical

One of the earliest legal precedents in this area was established in 1914 when a physician removed a tumor from the abdomen of a patient who had consented to only a diagnostic procedure. The judge in this case ruled that the physician was liable for battery because he violated an "individual's fundamental right to decide what is being done with his or her body."

How about "no"?



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### Anatomy of a Malpractice Lawsuit

- Negligence theory
- Duty (Provider-Patient relationship)
- Standard of care (what would be customary?)
- Breach of the duty
- Harm



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### Anatomy of a Malpractice Lawsuit

- The physicians possessed, or should have possessed, the information which was allegedly not disclosed
- The physicians should reasonably have recognized that the alleged information would be material to the patient's decision to accept or reject the treatment
- Had the alleged information been supplied, neither the patient nor any reasonable person in similar circumstances would have undergone the treatment
- The information was not, in fact, supplied
- The unrevealed risks in fact materialized.



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## Anatomy of a Malpractice Lawsuit

Informed Consent

- What if I do nothing
- Treatment experimental
- Who will be involved in treatment
- What is involved with treatment



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## Anatomy of a Malpractice Lawsuit

Informed Consent

- In litigation lines can blur
- Can sue for negligence and/or informed consent
- Plaintiffs can amend claims mid suit



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## Negligence vs Informed Consent

- Both employ the "reasonableness standard."
- What would RPP do?
- Average qualified medical provider in your specialty in same circumstances.
- Not platinum standard.



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### How Much to Consent?

- “The physicians should **reasonably have recognized** that the alleged information would be **material** to the patient’s decision to accept or reject the treatment.”
- Not every risk, falls back to a reasonableness standard.
- Should include the most prevalent and/or serious risks.
- Remember third element, **if patient knew about the risk, they would have rejected treatment.**
- No duty to disclose risk of erroneous diagnosis.



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### Case Study

- The patient presented to the physician with pain in his neck and back after falling from an oil truck.
- Alleged the physician should have told him to return in two to three days if the pain continued.
- The patient claimed that had he been so told, he would have returned and been administered additional tests including x-rays and CAT scans, thus avoiding the paraplegia he eventually suffered.

• Is this an informed consent case?



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### Informed Consent Process AMA

The physician (not a delegated representative) should disclose and discuss:

- The diagnosis, if known
- The nature and purpose of a proposed treatment or procedure
- The risks and benefits of proposed treatment or procedures
- Alternatives (regardless of costs or extent covered by insurance)
- The risks and benefits of alternatives
- The risks and benefits of not receiving treatments or undergoing procedures



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### Case Study

- Patient meets with a surgeon to discuss benefits of proceeding with surgery.
- No risks were discussed.
- Prior to surgery, the patient returns to the office to sign forms.
- The medical assistant asks the patient to sign the hospital's generic informed consent form, and lists the correct procedure.
- Patient denies any discussion of risks.

•Was informed consent given?



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### Informed Consent Obstacles

- **Lack of basic information on the consent form.** Nature of the procedure, risks, benefits and alternatives not included almost a third of the time.
- **Ineffective provider-patient communication** and lack of shared decision-making between patient and provider.
- **Lack of consideration of the health literacy** (not to mention English literacy) of patients when developing informed consent communication forms and other materials.
- **Lack of consideration of cultural issues** of patients when developing informed consent communication forms and other materials.



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### Case Study

- Patient signs hospital's generic informed consent form which lists standard infection, loss of blood, injury to organs, and death as risks.
- Form does not list specific procedure.
- Physician records in progress note, "risks and alternatives discussed."
- Patient denies any discussion of risks.

•Was informed consent given?



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**Informed Consent Best Practices**

- Do not assume that patients understand the medical terms.
- Decision aids (digital media, pictures, exemplars, websites, etc.) to break down complex topics.
- Make use of everyday language instead of medical jargon in communicating with patients or substitute decision makers.
- Consider the patient's cultural or language preferences.



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**Informed Consent Best Practices**

- Allow patients time to consider the information provided. (More than one visit?)
- Overcome language barriers and use language services.
- Use more open-ended questions to elicit information regarding patients' needs and preferences.
- Encourage patients to ask questions.



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**Informed Consent Best Practices**

- Ask the patient to explain back his or her understanding of the procedure and expected results.
- Include the family/support person in the discussion when available.
- Follow up with a phone call the day before surgery or a procedure.
- Use specialty specific forms in addition to any generic hospital forms.



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### Informed Consent Best Practices

- Avoid guarantees of an outcome.
- Do not suggest known complications should or will not occur.



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### Case Study

- Patient speaks broken English.
- Cannot read English.
- Surgeon explains surgical procedure, risk & benefits, hands patient generic hospital informed consent form.
- Patient has a family member read for him and signs.
- Was informed consent given?



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### Specialty-Specific Requirements

- The American College of Obstetrics and Gynecology has developed detailed guidelines for informed consent issues related to sterilization and carrier testing for cystic fibrosis. [ACOG 2004]



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### Informed Consent Form – Federal Law

- Name and signature of the patient, or if appropriate, legal representative
- Name of the hospital/office
- Name of procedure(s)
- Name of all practitioners performing the procedure and individual significant tasks if more than one practitioner
- Risks
- Benefits
- Alternative procedures and treatments and their risks
- Date and time consent is obtained
- Statement that procedure was explained to patient or guardian
- Signature of person witnessing the consent
- Name and signature of person who explained the procedure to the patient or guardian

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### Who Gives Consent?

- The incapacitated patient
- The minor patient
- The elder patient
- The unconscious patient

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### Who Gives Consent?

- Healthcare proxies
- Guardians
- Parents of minors
- Emancipated or mature minors

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## Exceptions to Consent

- Emergencies
- Changed surgical circumstances
- To avoid harm
- The incompetent patient (need for legal intervention)



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## Case Study

- PCP of a 75 year old gentleman with multiple diseases including metastatic lung cancer.
- Potential side effects of his cancer treatment included, "drowsiness, dizziness, lightheadedness, fainting, altered consciousness, and sedation."
- Doctor did not document a discussion about these risks.
- The patient loses consciousness while driving a runs over a pedestrian in a crosswalk.
- The pedestrian sues the doctor for not providing a warning against driving while on these medications.



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## Physician Third Party Liability

- Recognized in Massachusetts and other states.
- Here have a narrow third party duty to public to warn patient about side effects of medications for activities such as driving, operating heavy machinery, etc.

You must document these conversations explicitly.



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## Defending an Informed Consent Claim

- The informed consent *form* alone is important to have, but we are defending a process, not a form.
- Keep in mind, plaintiffs cannot deny they signed the form, but often deny any discussions about it.
- The more specific a form, the more defensible. The more generic, the more problematic.
- Documentation of the conversation can be key.
- The duty to provide informed consent is *non-delegable*.



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## Best Practices

- Be familiar with hospital/group policies on Informed Consent
- Informed consent is a process and a duty, not a form.
- The form can help to memorialize the process, particularly if not rubber stamped.
- Specific information relative to the procedure needs to be documented.
- Do not delegate consent discussion.
- Document in your progress, H&P, etc. about the conversation.
- References, videos, pictures, websites, all helpful.
- EHR templates, alerts or checklists?



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## Questions / Discussion



A great question  
doesn't simply inform...  
it enlightens.



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## Contact Information

Chad Brouillard, MA, JD  
Foster and Eldridge, LLP  
[CBROUILLARD@fosteld.com](mailto:CBROUILLARD@fosteld.com)

Jim Purcell  
Taylor Healthcare  
[James.Purcell@taylor.com](mailto:James.Purcell@taylor.com)

Glen Gilman  
Taylor Healthcare  
[Glen.Gilman@taylor.com](mailto:Glen.Gilman@taylor.com)



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