

# Legal Aspects of CDS

## Defining the Problems

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# Scenario 1

- A professional society assembles a 12 member team to systematically and exhaustively review the literature and devise recommendations about appropriate care using the society's carefully honed internally developed process. The guideline is published in the society's flagship journal.
- Who owns what? Does the society own a copyright? To what are they entitled?

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# Scenario 2

- A group unaffiliated with the professional society marks up the guideline using GEM and creates a clinical decision support tool that they sell to a major EHR vendor. The vendor offers the decision support as a major component of its next revision.
- Has the professional society's copyright been violated?
- Is the professional society due a royalty? From whom?

# Scenario 3

- A clinician reading the guideline interprets it and applies his understanding to treat a patient in a manner consistent with the guideline. The patient suffers a serious adverse outcome. The guideline incorporates the disclaimer shown on the next slide.
- Is the physician shielded by his/her use of the guideline?

# Disclaimer

- This Clinical Practice Guideline was developed by a physician volunteer Work Group based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This Clinical Practice Guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

# Traditional Methods of Proof in Malpractice Litigation

- Plaintiff must prove:
  - A duty was owed to the plaintiff
  - MD breached that duty
  - Breach caused an injury
  - Breach caused damages to the plaintiff
- Expert witnesses testify as to whether defendant breached duty owed to the plaintiff by not exercising the customary standard of care of a reasonable member of the profession in good standing
- Customary standard of care may not coincide with scientifically formulated, evidence-based guideline

# Using Guidelines as Affirmative Defense in Malpractice Actions

- MD sued for negligence would assert the use of the guideline as affirmative defense
- If all the facts in the complaint are true, so long as the doctor followed the guideline, the plaintiff's suit is defeated
- The Maine Medical Liability Demonstration Project (1990-99)
  - 20 common procedures
  - Anesthesia, ED, OB-GYN, radiology
  - Goal: resolve malpractice claims without litigation
  - 87-92% of physicians in each specialty participated
  - Test ordering decreased
  - Only one eligible malpractice case advanced to trial

# Hearsay Rule Limitations

- An expert relying on CPG to aid testimony may be subject to hearsay rule limitations
- Use of information gathered by one person from another concerning some event, condition, or thing of which the first person had no direct experience to prove the truth of what is asserted is generally not allowed.

# Courts Confront CPGs

- *Hinlicky v. Dreyfuss* – NY high court confronted admissibility of guidelines as evidence

# Evidence in *Hinlicky*

- 71 YO underwent carotid endarterectomy
- Surgery successful but 25 days after discharge, pt suffered MI and died
- Estate sued internist, surgeon, anesthesiologist alleging negligence caused death by not obtaining preoperative cardiac evaluation “to insure that [the patient’s] heart could tolerate surgery”
- Anesthesiologist testified he consulted CPG published by Am Heart Assoc and Am College of Cardiology and incorporated the guidelines into his practice

# Hearsay?

- Plaintiff's lawyer objected to further questions concerning guidelines citing the hearsay rule
- Judge decided **not** to exclude guidelines citing "Learned Treatise" exception to hearsay rule
  - "...statements contained in published treatises, periodicals, or pamphlets on a subject of ...medicine or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice [are not excluded by the hearsay rule, even though the declarant is available as a witness]. (Federal Rules of Evidence)
- Jury ruled for the defendants
- Plaintiff appealed: challenged trial court's decision to admit GL algorithm into evidence

# The Appeal

- Court attempted to distinguish between classic hearsay and what occurred at trial
  - Flowchart was admitted as a “demonstrative aid” to show anesthesiologist’s decision making process
  - It was not admitted as proof that the information contained in the guideline was correct
- Despite suggestion Hinlicky would have broad implications on tort law, little progress
- Awaiting action by state legislatures

# Scenario 4

- A clinician treating a patient is advised by a clinical decision support system in his EHR “based” on a professional society guideline to provide care in a particular way. The patient suffers a serious adverse event and outcome.
- Besides the treating clinician, is the EHR vendor liable or protected by the “learned intermediary” defense doctrine?
- Do strict product liability or negligence standards apply to CDS?

# Negligence

- Creation of an unreasonable risk of harm to others within the zone of foreseeable danger, as a result of behavior which, though it does not imply intent to injure others, nevertheless falls short of the standards that a reasonable man of ordinary prudence would meet under the circumstances
- Implies a failure to live up to community's ideal of reasonable care
- Malpractice: patient injuries are judged under a negligence standard

# Liability Without Fault

- Purpose: furthers public safety
- Supplier invites public to use his product by making it available. When supplier places product in stream of commerce to earn a profit he should be liable for any injury caused by a defect in product
- Supplier is in best position to anticipate and control risks of harm
- Injured party may be less able to absorb risk of catastrophic loss than a business
- Manufacturererscan spread costs throughout society by increasing cost of product
- Social value of tort compensation may be deterrence of sale of dangerous products

# Special Liability of the Seller

- For physical harm to a user/consumer
- Even when Seller has exercised all possible care in preparation and sale of product

Restatement (Second) of Torts

# Strict Liability vs Negligence Standards

- Is computer software a good or a service?
- Good
  - Available in tangible format
  - May be owned
  - Exists through time
- Service
  - Information contained in software is intangible
  - Output of program provides a service

# Strict Liability vs Negligence Standards: Who is liable?

- Strict liability
  - Manufacturer, retailer
  - Practitioner using software
- Negligence: Software-using healthcare providers who:
  - Are negligent in selection, installation or maintenance of programs
  - Negligently rely on improper computer-generated info
  - Negligently supervise or administer computer-controlled equipment

# Strict Liability vs Negligence Standards: Proof Required

- Strict: Product is examined
  - Product reached consumer in defective condition
  - Product was expected to reach and did reach consumer without substantial change in the condition in which it was sold
  - Product was used in an intended and reasonably foreseeable manner
  - Product was proximate cause of injury
  - No standard of care

# Negligence Standard: Proof Required

- Practitioner failed to meet an appropriate standard of care and that failure caused plaintiff's injury
- Finding the right defendant is challenging
- Expert testimony determines a reasonable standard and conformity with that standard