Decline and Fall of Medical Self-Regulation

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Roadmap

What is medical self-regulation?

Decline of medical self-regulation

Futility safe harbors
Mandated disclosures

Self-Regulation

12:10 – 12:40

12:40 – 1:00
Entry
Medical Board

Regulation
Privileging & credentialing

Torts
Malpractice
Tort law “gives the medical profession . . . the privilege, which is usually emphatically denied to other groups, of setting their own legal standards of conduct, merely by adopting their own practices.”

Defence
Delegation

Custom is what experts say

Jury makes no normative, value judgments

Jury does not say “X is what docs normally do, but they OUGHT to do x+1.”

Normally -

Custom is just evidence on standard of care

T. J. Hooper 60 F.2d 737 (2d Cir. 1932)
“In most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged . . . . It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.”

Med Mal - Custom defines standard of care

Decline of self-regulation

Helling v. Carey, 519 P.2d 981 (Wash. 1974)

Futility red lights

Mandated disclosures
“If surrogate directs [LST] . . . provider that does not wish to provide . . . shall nonetheless comply . . .”
“Health care . . . may not be . . . denied if . . . directed by . . . surrogate”
Mandated Disclosures:
Introduction to informed consent

Legal duty of informed consent usually **framed** in terms of tort and negligence

Informed consent is **one type** of medical malpractice

What to disclose?
Not everything
You can’t send patient to med school

2 main ways to **measure** MD duty

<table>
<thead>
<tr>
<th>Material risk</th>
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<td>20+ states</td>
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<tr>
<th>Reasonable MD</th>
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<td>20+ states</td>
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Reasonable physician
- Duty measured by custom
- Like malpractice
- What a prudent physician would disclose under circumstances

Material risk
- Duty measured by patient needs
- What a reasonable patient would deem significant

Mandated Disclosures:
Problems with informed consent

Not happening
e.g. EOL treatment

At least in material risk jurisdictions, duty to disclose EOL options has existed for decades

Health Care Costs in the Last Week of Life

Associations With End-of-Life Conversations

Bouchra Chene, MD; Alvin A. Wright, MD; Helen A. Mustian, PhD; Matthew J. Neumann, BS; Matthew L. Makuc, PhD; Cong C. Earl, MD; Susan D. Hsiung, MD; Paul K. Marur, MD, MPH; G. Prigov, PhD

Background: Life-sustaining medical care of patients with advanced cancer at the end of life (EOL) is costly. Patient-physician discussions about EOL wishes are associated with lower rates of intensive interventions.

Methods: Funded by the National Institutes of Mental Health and the National Cancer Institute. Coping With Cancer in a-hospitalized multi-institutional study of 627 patients with advanced cancer. Patients were interviewed at a home and were followed up through death. Costs for intensive care unit and hospital stays, hospice care, and life-sustaining procedures (eg, mechanical ventilation and resuscitation) received in the last week of life were aggregated. Generalized linear models were applied to test for cost differences in EOL care. Propensity score matching was used to reduce selection biases.

Results: Of 540 participants, 981 (31.2%) reported EOL discussions at baseline. After propensity score matching, the remaining 453 patients did not differ in socio-demographic characteristics. Multivariable regression analysis adjusted by quintiles of propensity scores and significant covariates. Only 31% of patients with advanced cancer had EOL discussions. In aggregate costs ($3777) for patients who reported EOL discussions compared with $5276 for patients who did not, a cost difference of $1,499 (P = .003). Patients with higher costs had worse quality of death in their final week. (Fournier, production 2007, P = .0017; P = .009).

Conclusions: Patients with advanced cancer who reported having EOL conversations with physicians had significantly lower health care costs in their final week of life. Higher costs were associated with worse quality of death.

Arch Intern Med. 2009;169(23):480-488
Late timing

<table>
<thead>
<tr>
<th>Months Between Diagnosis and Death</th>
<th>Patients, n</th>
<th>Median Days Between End-of-Life Care Discussion and Death (OS)</th>
<th>Patients Who Have Discussion Before Death, %</th>
</tr>
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<tbody>
<tr>
<td>&lt;1</td>
<td>113</td>
<td>14 (IQR 10)</td>
<td>NA</td>
</tr>
<tr>
<td>1-3</td>
<td>282</td>
<td>28 (IQR 14)</td>
<td>47</td>
</tr>
<tr>
<td>3-6</td>
<td>220</td>
<td>59 (IQR 47)</td>
<td>74</td>
</tr>
<tr>
<td>6-9</td>
<td>126</td>
<td>47 (IQR 42)</td>
<td>92</td>
</tr>
<tr>
<td>9-12</td>
<td>89</td>
<td>46 (IQR 29)</td>
<td>85</td>
</tr>
<tr>
<td>&gt;12</td>
<td>89</td>
<td>46 (IQR 42)</td>
<td>85</td>
</tr>
<tr>
<td>Overall</td>
<td>599</td>
<td></td>
<td>NA</td>
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EOL discussion

Earlier hospice referral
Better patient QOL
Better family bereavement

Legislative Finding:

“patients with reduced life expectancy due to advanced illnesses . . . are often **unaware** of their legal rights, particularly with regard to controlling end-of-life decisions.”

Mandated Disclosures:

Statutory mandates
1991

Patient Self Determination Act

Duty on facilities
Upon admission
Apprise of AD rights under state law

Last 5 years at state level
healthcare facilities must determine “which of those individuals who do not have a [POLST] should be offered the opportunity to complete [one].”

Utah Admin. R. 432-31 (2011)
When . . . provider diagnoses . . . terminal illness, . . . shall, upon the patient’s request, provide . . . comprehensive information and counseling regarding legal end-of-life options.

**Prognosis** with or without disease-targeted treatment

Right to accept **disease-targeted treatment**, with or without palliative care

Right to refuse or withdraw from **life-sustaining treatment**

Right to have comprehensive **pain** and symptom management

Meaning and availability of **hospice** care

Right to give individual health care **instruction** (POLST; AD)

Attend to emotional cues, ability to absorb...

**2009**

Patient’s Bill of Rights for Palliative Care & Pain Management  (Vt. Stat. tit. 18 § 1871)
Maryland S.B. 546, H.B. 30

Ariz. S.B. 1304

2010

Palliative Care Information Act
NY Pub. Health L. 2997c

Similar to CA
But better

**CA:** “upon the patient’s request”

**NY:** “shall offer to provide”
2011
Palliative Care Access Act
NY Pub. Health L. 2997d

2012
Massachusetts Act Improving the Quality of Health Care & Reducing Costs through Increased Transparency, Efficiency & Innovation

2014
Hospital Licensure Regulations
105 CMR. 130.1900
Mandated Disclosures: Enforcement

New York
$2000 civil penalty
$5000, if repeat violations
1 year prison, if willful

California
No separate penalties
But **defines** duties under common law

Michelle Hargett
terminal pancreatic cancer

**Not Only EOL**
Other gaps

Other mandates

Breast reconstruction coverage

Breast density
Cal. S.B. 1538 (2013)

Mandated Disclosures:
Opposition

4 types of opposition to mandated disclosures

Mandated Disclosures:
Opposition 1
“Laws . . . should not mandate . . . provision . . . of information . . . that, in the physician’s clinical judgment and based on clinical evidence and the norms of the profession, are not necessary or appropriate . . . .”
In contrast, government must avoid regulating the content of the individual clinical encounter without a compelling and evidence-based benefit to the patient, a substantial public health justification, or both.
“misrepresentation and misuse of medical information in the pursuit of partisan aims”

“[L]egislatures have been encroaching on the realm of medicine . . . declaring medical ‘facts,’ specifying or forbidding medical procedures, and dictating to doctors what they must say”

Response

Let’s not throw the baby out with the bath water.
A Comparison of Methods to Communicate Treatment Preferences in Nursing Facilities: Traditional Practic
ices versus the Physicians Orders for Life-Sustaining Treatment (POLST) Program.

Susan E. Hickman, PhD, Christine A. Nelson, PhD, RN, Nancy A Perrin, PhD, Alvin H Moss, MD, Bernard J Hammes, PhD, and Susan W. Tolle, MD.

Mandated Disclosures: Opposition 3
“most common and least successful regulatory technique in American law”

Response

Electronic Prompt to Improve Outpatient Code Status Documentation for Patients With Advanced Lung Cancer

Jennifer S. Tamke, Joseph A. Casey, Emily R. Gallagher, Wade A. Jackson, Inga T. Zomes, Alima Maarkeddu, Elise L. Park, and William P. Ny

Conclusion
Optional prompts may improve the rate and timing of code status documentation in the EHR and warrant further investigation.
Mandated Disclosures: Opposition 4

Wrong focus on **content** of information, than **manner** of delivery

Response

SDM
Problems do arise in 5 in 100 cases.
Next 5 years:

**Safe harbor** for using “certified” PtDA

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**Conclusion**

113TH CONGRESS
2nd Session

**H. R. 4106**

To provide for the development and dissemination of clinical practice guidelines and the establishment of a right of removal to Federal courts for defendants in medical malpractice actions involving a Federal payor, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

February 27, 2014

"This is their new big carrot and stick method."