Legal Developments in Clinical Bioethics

HCA Webinar ● February 4, 2014

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Mandated Disclosures

1. Mandated disclosures
2. The unbefriended
3. Jahi McMath
4. Marlise Munoz

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

Material risk
20+ states

Reasonable MD
20+ states

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

Background: Life-sustaining medical care of persons with advanced cancer at the end of life (EOL) is costly. Little is known about physician discussions about EOL care, which are associated with fewer rates of interventions.

Methods: A national survey assessed 2,734 patients with advanced cancer. Patients were interviewed at baseline and were followed up over the course of care. Subsequent care was assessed at the time of hospitalization or death. EOL care was defined as interventions to prevent death.

Results: Of 2,734 patients, 57% had an EOL discussion. Only 31% had an EOL discussion, with less aggressive medicine. Only 31% had EOL discussions. EOL discussion less aggressive medicine

JAMA

Associations Between End-of-Life Discussions, Patient Mental Health, Medical Care Near Death, and Caregiver Bereavement Adjustment

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

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.”

Not just EOL
Other gaps
Other mandates

Mandated Disclosures:
Statutory mandates

Breast reconstruction coverage

Breast density
Cal. S.B. 1538 (2013)
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)
1996
Michigan Dignified Death Act
Mich. Comp. Laws 333.5651

2008
Right to Know End-of-Life Options Act
Cal. H&S Code 442.5

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

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

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 . . . .”

**Mandated Disclosures: Opposition 2**
CATEGORIES OF LIFE SUSTAINING TREATMENTS


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

More Than You Wanted to Know: The Failure of Mandated Disclosure

Omri Ben-Shahar & Carl E. Schneider
(April 2014)

“most common and least successful regulatory technique in American law”
Electronic Prompt to Improve Outpatient Code Status Documentation for Patients With Advanced Lung Cancer
Sjouke M. Steed, Joseph J. Czer, Emily R. Gallagher, Yindu S. Jhala, Jeff T. Jones, Alice Richland, Lane R. Park, and William F. Truog
See accompanying editorial on page 485

Conclusion
Mandated Disclosures: Opposition 4

Ongoing process
NOT a one-time event

Focus on information **content** than on **manner** of delivery

Must incorporate lessons from **PtDA**

Next 5 years:
**Safe harbor** for using “certified” **PtDA**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Yes (n=75)</th>
<th>No (n=70)</th>
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<tbody>
<tr>
<td>Medical care received during the last week of life, No. (%)</td>
<td>2 (2.7)</td>
<td>10 (14.3)</td>
</tr>
<tr>
<td>Intensive care unit stay</td>
<td>1 (1.3)</td>
<td>10 (14.3)</td>
</tr>
<tr>
<td>Ventilator use</td>
<td>1 (1.3)</td>
<td>6 (8.6)</td>
</tr>
<tr>
<td>Resuscitation</td>
<td>1 (1.3)</td>
<td>6 (8.6)</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>1 (1.3)</td>
<td>6 (8.6)</td>
</tr>
<tr>
<td>Intensive hospital stay</td>
<td>2 (2.7)</td>
<td>5 (7.1)</td>
</tr>
<tr>
<td>Intensive hospital stay &gt;1 wk</td>
<td>2 (2.7)</td>
<td>5 (7.1)</td>
</tr>
<tr>
<td>Intensive hospice stay</td>
<td>1 (1.3)</td>
<td>8 (11.4)</td>
</tr>
<tr>
<td>Intensive hospice stay &gt;1 wk</td>
<td>1 (1.3)</td>
<td>6 (8.6)</td>
</tr>
<tr>
<td>Place of death, No. (%)</td>
<td>1 (1.3)</td>
<td>9 (13.2)</td>
</tr>
<tr>
<td>Intensive care unit</td>
<td>1 (1.3)</td>
<td>9 (13.2)</td>
</tr>
<tr>
<td>Hospital</td>
<td>15 (20.7)</td>
<td>18 (26.5)</td>
</tr>
<tr>
<td>Intensive hospice</td>
<td>1 (1.3)</td>
<td>3 (4.4)</td>
</tr>
<tr>
<td>Home</td>
<td>47 (63.1)</td>
<td>38 (55.9)</td>
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</table>
Decision Making for Patients without Surrogates

Incapacitated
No agent (DPAHC)
No guardian
No surrogate

Wider & more flexible
\textit{e.g.} “close friend”

4% of 1.3 million in nursing homes
5% of 500,000/year who die in ICU

Most jurisdictions: only mechanism is court-appointed \textbf{guardian}

\textbf{BUT} \quad Slow
\quad Expensive
\quad Unavailable

In entire USA, \textbf{only a few} mechanisms that are accessible, quick, convenient, and cost-effective
The interdisciplinary team shall oversee the care of the resident utilizing a team approach.

- the resident’s attending physician
- a registered professional nurse with responsibility for the resident
- other appropriate staff in disciplines as determined by the resident's needs
- where practicable, a patient representative
COI
patient representative only “where practicable”

Early
Litigation just getting started

More external oversight =
Slow, cumbersome, expensive
Risks of under-treatment & over-treatment

Jahi McMath

Jahi McMath:
Case History
“An individual . . . . is dead . . . who has sustained either
(1) irreversible cessation of circulatory and respiratory functions, or
(2) irreversible cessation of all functions of the entire brain.”
Cal. H&S Code 7180-81

“When an individual is pronounced [brain] dead . . ., there shall be independent confirmation by another physician.”

“independent . . . physician”

Paul Fisher
Stanford Child Neurology
Christopher Dolan

Jahi McMath: Lawsuits

Claim: CA should be like NJ

“Death . . . shall not be declared upon the basis of neurological criteria . . . when the licensed physician . . . has reason to believe, . . . would violate the personal religious beliefs of the individual.”

“. . . hospital shall [provide] next of kin with a **reasonably brief period of accommodation** . . . . continue only previously ordered cardiopulmonary support. No other medical intervention is required.”

Cal. H&S Code 1254.4

“**Reasonably brief period** . . . amount of time afforded to gather family or next of kin at the patient's bedside.”

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**No adjudication on the merits**

**TRO only**

Stopgap to preserve status quo pending hearing

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**Challenge to what is settled**

Brain death laws: early 1980s

**Prognostic mistrust**

Racial mistrust

Religious pluralism
BUT - with changed societal attitudes, time to reevaluate??

Views About End-of-Life Treatment Over Time
% of U.S. adults

<table>
<thead>
<tr>
<th></th>
<th>1990</th>
<th>2005</th>
<th>2013</th>
<th>Diff. 90-13</th>
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<tbody>
<tr>
<td>There are circumstances in which a patient should be allowed to die</td>
<td>73</td>
<td>70</td>
<td>66</td>
<td>-7</td>
</tr>
<tr>
<td>Doctors and nurses should do everything possible to save the life of a patient in all circumstances</td>
<td>15</td>
<td>22</td>
<td>31</td>
<td>+16</td>
</tr>
<tr>
<td>Don't know</td>
<td>12</td>
<td>8</td>
<td>2</td>
<td>-9</td>
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Marlise Munoz

Marlise Munoz: Case History
“A person may not withdraw or withhold life-sustaining treatment under this subchapter from a pregnant patient.”

Tex. H&S Code 166.049

Marlise Munoz: Lawsuit
“Life-sustaining treatment . . . sustains the life of a patient and without which the patient will die.”

Tex. H&S Code 166.001

Contrast *McMath*:

Here, there was an adjudication on the merits.

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CAUSE NO. 096-27089-14
ELICK MUÑOZ, AN INDIVIDUAL ANO HUSBAND, NEXT FRIEND OF MARILISE MUÑOZ, DECEDED VS.
JOHN PETER SMITH HOSPITAL, AND CODE 1 THROUGH 10, INCLUDES

IN THE DISTRICT COURT
TARRANT COUNTY, TEXAS
9TH JUDICIAL DISTRICT

JUDGMENT

All relief not expressly granted herein is denied.

SIGNED this _3rd_ day of January 2014.

R. H. WALLACE, P. J., PRESIDING

Judgment not novel

But stirred dormant controversies

Having considered these matters, the Court finds:

1. The provisions of § 166.049 of the Texas Health and Safety Code do not apply to Marilise Muñoz because, applying the standards used in determining death set forth in § 671.001 of the Texas Health and Safety Code, Mrs. Muñoz is dead.

2. In light of that ruling, the Court makes no rulings on the Plaintiff’s constitutional challenges to § 166.049.
Other AD **limitations** ripe for reexamination

**EXAMPLE:**
Oral food & fluid

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