Life-Sustaining Treatment Guidelines Work Group – Final Report

Joint Commission on Health Care
September 19, 2017 Meeting

Andrew Mitchell

Senior Health Policy Analyst

Work Group Mandate

- In 2016, Delegate Stolle requested that the JCHC study the current legal and regulatory environment on life-prolonging care, resulting in the JCHC staff study: "Development of Life-Sustaining Treatment Guidelines"
- The JCHC voted in favor of Policy Option #3 to include in the 2017 work plan the formation of a work group
- By letter of the JCHC Chair, the work group was directed to:
  - Study issues surrounding the provision of life-sustaining treatment decisions in Virginia
  - Continue and extend discussions initiated by a work group formed as part of the "Development of Life-Sustaining Treatment Guidelines" study
  - Focus on options for preventing or improving outcomes of life-sustaining treatment decision conflict and report back to the JCHC in 2017

Background

- § 54.1-2990 of the Code of Virginia addresses circumstances in which a physician refuses to provide life-sustaining treatment that s/he determines to be medically or ethically inappropriate, and that determination is in conflict with a treatment preference expressed by a patient or proxy (e.g., Advance Directive, instructions by patient's designated decision-maker)
- § 54.1-2990 describes certain procedures to be followed by the physician who refuses to provide health care s/he determines to be inappropriate and provides a 14-day timeframe for resolution
- However, the Code is silent on permissible treatment decisions if 14 days have passed but consensus has not been reached

Work Group Participants

- Bon Secours Health System
- Carilion Clinic
- Department of Aging and Rehabilitative Services
- Department of Health Professions
- disAbility Law Center of Virginia
- Inova
- LeadingAge
- LifeNet Health
- Mary Washington Health Care
- Medical Society of Virginia
- Riverside Health System
- Sentara Healthcare
- The Arc of Northern Virginia
- The Family Foundation
- University of Virginia Health System
- Virginia Association for Hospices & Palliative Care
- Virginia Association of Centers for Independent Living
- Virginia Association of Health Plans
- Virginia Catholic Conference
- Virginia Commonwealth University Health System
- Virginia Department of Health
- Virginia Health Care Association
- Virginia Hospital and Healthcare Association
- Virginia Nurses Association
- Virginia Society for Human Life
- Virginia Trial Lawyers Association

Work Group Areas of Focus

- The Work Group identified three workstreams on which to focus:
  - Literature/data on contextual factors surrounding disputes
  - Data on the frequency and characteristics of disputes in Virginia
  - Continued revisions to § 54.1-2990 to increase statutory clarity on resolution of disputes

Contextual Factors

- Nationally, approximately 35% of deaths take place in inpatient hospital settings
  - Of those deaths, approximately 80% occur after decisions are made to withhold or withdraw life-sustaining treatment
- Treatment decision conflicts between clinicians and families are estimated to:
  - Arise frequently in ICU setting (e.g., 22% to 48% of ICU admissions)
  - Account for one-third to one-half of conflicts in the ICU
- Disputes are regularly identified as the single biggest ethical dilemma facing U.S. hospitals (e.g., over 50% of ethics consultations focus on withholding or withdrawing treatment)
  - However, before disputes become intractable, consensus is reached in vast majority (over 95%) of cases

Contextual Factors (2)

- Common factors associated with treatment decisions disputes between patients/families and providers include:
  - Different goals of care
  - Differences in interpretation of likelihood of success
  - Distrust in patient/family-provider relationship
- Common sources of conflict related to treatment decision disputes in end of life care include:
  - Lack of psychological support for families
  - Sub-optimal facility decision making processes
  - Perceived disregard for family or patient preferences
- Factors that protected against conflict include:
  - Bedside manner
  - More provider/family/patient discussion

Contextual Factors (3)

- Among nurses and physicians, prolonged aggressive treatment when the prognosis is poor has been identified as the most common cause of moral distress
- Moral distress is positively correlated with intention to leave a position and, at any given time, 10-25% of clinicians are considering leaving their position now due to moral distress
- In Virginia, the UVA Health System has conducted over 75 consults in the past 10 years related to moral distress, with 40% relating to end-of-life situations or treatment decision conflicts

Frequency/Characteristics of Disputes in Virginia – Survey

- A survey was developed to quantify and characterize instances of life-sustaining treatment disputes between patients/families and providers
- Data were collected from health systems operating acute care hospitals in Virginia
- 84% (16/19) of health systems responded to the survey, representing 90% (66/73) of general acute care hospitals in Virginia

Frequency/Characteristics of Disputes in Virginia – Survey Findings

- 56% of health systems surveyed (9/16):
  - Have a written, formalized process for handling situations of intractable treatment decision conflict between the health care team and patients/families/surrogate decision makers
    - All with a written, formalized process indicate how patients/family members/patient agents are able to participate in the process
- Of the 8 health systems surveyed without a written, formalized process:
  - All but one see a need for such a process
  - The majority (5/8) have not established such a process due to lack of legislative clarity

Frequency/Characteristics of Disputes in Virginia – Survey Findings (2)

- Among health systems with a process for handling situations of intractable treatment decision conflict:
  - Over 40 cases went through the process in the last 12 months
  - Across all 40 cases:
    - 38% were resolved because the health care team and the patient or patient's agent came to consensus
    - 5% resulted in withholding or withdrawing life-sustaining treatment over patients' families objections
    - 2% were resolved because the patient was transferred to another facility or physician
    - 0% involved litigation
- Among health systems without a formalized process,
  - Three estimated that they would see five to ten cases per year
  - Three indicated that they would see ten to twenty cases per year

Frequency/Characteristics of Disputes in Virginia – Future Data Collection

- Multiple workgroup participants expressed a desire to build off of the knowledge gained in this survey to more routinely collect data going forward

Continued revisions to § 54.1-2990 – Guiding Principles

- Build off of revisions drafted in 2016 as part of the "Development of Life-Sustaining Treatment Guidelines" study
- Address stakeholder concerns and provide safeguards from both patient and provider perspectives
- Address incompleteness/imbalance in current Statute (revisions to the statute should outline a complete process; specify an endpoint)
- Reflect principles of procedural due process

Continued revisions to § 54.1-2990 – Highlights

Current Statute provisions	Additional safeguard(s) proposed

• Physician is not required to provide medically/ethically inappropriate treatment	• <u>Physician determination of appropriateness bounded by:</u>
	  • Explicitly requiring patient's medical condition as basis of determination
	  • Preventing determination to be based on disability and other patient attributes that are not directly related to patient's medical condition

• Physician shall make a reasonable effort to inform patient of reasons for the decision not to provide medically/ethically inappropriate treatment	• <u>Add two levels of requirements of hospitals/physicians surrounding physician's decision:</u>
	  • Four process steps to formally review physician's decision (e.g., 2nd medical opinion; interdisciplinary medical committee review)
	  • Five points of written information required to be provided to patient/patient's agent: (e.g., right of the patient to: an independent medical opinion; participate in medical review committee process; seek available remedies under the law)

Continued revisions to § 54.1-2990 – Highlights (2)

Current Statute provisions	Additional safeguard(s)s proposed
• Physician shall make a reasonable effort to transfer the patient and provide patient's agent 14 days to transfer	• Retains requirements to facilitate transfer and provide 14 days for transfer
• During 14-day window, life-sustaining treatment must continue	• Retains requirement to continue life-sustaining treatment and requires hospital to facilitate access to patient's medical records

Continued revisions to § 54.1-2990 – Highlights (3)

New Statute provisions	Safeguard(s) proposed

• Allows withdrawal/withholding of life-sustaining treatment after 14 days if no transfer possible	• For artificial food and nutrition:
	  • Prohibits withdrawal/withholding if its removal would be the sole mechanism to hasten death
	  • Allows withdrawal/withholding if its provision would hasten death, be harmful or medically ineffective, or be contrary to the patient's wishes

• Creates liability protections for physicians who abide by process requirements	• Following process requirements creates presumption of standard of care (civil liability) and protects from criminal liability absent gross negligence

Policy Options

- Take No Action
- Based on revisions to § 54.1-2990 proposed by the Work Group, introduce legislation to amend § 54.1-2990 of the Code of Virginia
  - Please see slides 19-28 for a complete version of the revised Code

Public Comment

Written public comments on the proposed options may be submitted to JCHC by close of business on October 12, 2017.

Comments may be submitted via:

- E-mail: jchcpubliccomments@jchc.virginia.gov
- Fax: 804-786-5538
- Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia 23218

Comments will be provided to Commission members and summarized during the JCHC's November 21st decision matrix meeting.

(All public comments are subject to FOIA release of records)

Work Group proposed revisions to § 54.1-2990

§ 54.1-2990. Medically unnecessary treatment not required; procedure when physician refuses to comply with an advance directive or a designated person's treatment decision; mercy killing or euthanasia prohibited

Nothing in this article shall be construed to require a physician to prescribe or render health care to a patient that the physician determines to be medically or ethically inappropriate. *The physician, using reasonable medical judgment in determining the medical or ethical appropriateness of treatment, shall base his determination solely on the patient's medical condition, not the patient's age or other demographic status, disability, or diagnosis of Persistent Vegetative State (PVS), except to the extent that the patient's age or other demographic status, disability, or diagnosis of Persistent Vegetative State (PVS) relate to the patient's medical condition.*

Work Group proposed revisions to § 54.1-2990 (2)

~~However, i~~*I*n such a case *that the physician determines health care to be medically or ethically inappropriate*, if the physician's determination is contrary to the request of the patient, the terms of a patient's advance directive, the decision of an agent or person authorized to make decisions pursuant to § 54.1-2986~~, or a Durable Do Not Resuscitate Order~~, the *policies of the hospital in which the patient is receiving health care will be followed.*

Work Group proposed revisions to § 54.1-2990 (3)

Policies of the hospital that is equipped to provide life-sustaining treatment shall be documented and shall include, at a minimum, the following steps:

(1) Rendering of a second medical opinion;

(2) Review of the physician's determination by an interdisciplinary medical review committee, followed by issuance of its own determination on the appropriateness of requested treatment. The patient, agent or person authorized to make medical decisions pursuant to § 54.1-2986 will be afforded reasonable opportunity to participate in the medical review committee meeting;

(3) Written explanation of the decision reached during the medical review committee review process that will be included in the patient's medical record

Work Group proposed revisions to § 54.1-2990 (4)

If the patient, agent or person authorized to make medical decisions pursuant to § 54.1-2986 requests life-sustaining treatment that the attending physician determines to be medically or ethically inappropriate, the physician *or physician's designee* shall *document his decision in the patient's medical record and* make a reasonable effort to *provide* ~~inform~~*, in writing, to* the patient or the patient's agent or person with decision-making authority pursuant to § 54.1-2986*: the physician's* ~~of such~~ determination and the reasons for the determination~~.~~*, and; a copy of the hospital policies pursuant to this section.*

Work Group proposed revisions to § 54.1-2990 (5)

The hospital in which the patient is receiving health care shall make reasonable efforts to inform the patient or the patient's agent or person authorized to make decisions pursuant to § 54.1-2986, in writing: that the patient has the right under § 32.1-127.1:03 to obtain a copy of the patient's medical record; that the patient may obtain on his or her own behalf independent medical opinion; that under this section, the patient has the right to participate in the medical review committee meeting and may be accompanied by any trusted advisor to assist the patient, patient's agent, or person authorized to make decisions pursuant to § 54.1-2986 in understanding the proceedings, deliberations, and decision of the medical review committee; and that neither hospital policies and procedures nor any requirement of this section shall preclude the patient, patient's agent, or person authorized to make decisions pursuant to § 54.1-2986 from obtaining legal counsel to represent the patient or from seeking other remedies available at law; provided, however, that the patient or his or her legal counsel must provide a formal notice of such intention to the chief executive officer of the hospital prior to the date fourteen days following documentation of the decision of the physician in the patient's medical record.

Work Group proposed revisions to § 54.1-2990 (6)

~~If the conflict remains unresolved, the physician shall make a reasonable effort to transfer the patient to~~*If* another physician *or facility* ~~who~~ is willing to comply with the request of the patient, the terms of the advance directive, the decision of an agent or person authorized to make decisions pursuant to § 54.1-2986, ~~or a Durable Do Not Resuscitate Order.~~ *the physician currently attending the patient shall cooperate in transferring the patient to the second physician or facility.* The physician shall provide the patient or his agent or person with decision-making authority pursuant to § 54.1-2986 a reasonable time of not less than fourteen days *after documentation of the decision of the physician pursuant to this section in the patient's medical record* to effect such transfer. During this period, the physician shall*:* continue to provide any life-sustaining ~~care~~ *treatment* to the patient which is reasonably available to such physician, as requested by the patient or his agent or person with decision-making authority pursuant to § 54.1-2986*. The hospital in which the patient is receiving health care shall facilitate prompt access to medical records related to the treatment received by the patient in the facility pursuant to § 32.1-127.1:03.*

Work Group proposed revisions to § 54.1-2990 (7)

If, at the end of the 14-day period, the policies of the hospital in which the patient is receiving health care have been followed and the physician has been unable to transfer the patient to another physician who is willing to comply with the request of the patient, the terms of the advance directive, the decision of the agent or person authorized to make decisions pursuant to § 54.1-2986 despite reasonable efforts, the physician may cease to provide the treatment that the physician has determined to be medically or ethically inappropriate.

Work Group proposed revisions to § 54.1-2990 (8)

However, artificially administered nutrition and hydration: must be provided if, based on the physician's reasonable medical judgment, removal of artificially administered nutrition and hydration would be the sole mechanism that would hasten the patient's death; may be withdrawn or withheld if, based on the physician's reasonable medical judgment, providing artificially administered nutrition and hydration would:

(1) hasten the patient's death;

(2) be harmful or medically ineffective in prolonging life; or

(3) be contrary to the patient's or surrogate's clearly documented desire not to receive artificially administered nutrition or hydration.

In all cases, care directed toward the patient's pain and comfort shall be provided.

Work Group proposed revisions to § 54.1-2990 (9)

A health care provider who abides by the duties and requirements of § 54.1-2990 shall be presumed to have complied with the standard of care as set forth in § 8.01-581.20, absent clear and convincing evidence of gross negligence or willful misconduct by such health care provider. A health care provider who abides by the duties and obligations of § 54.1-2990 shall not be subject to criminal prosecution related to such actions or inactions and shall not be subject to disciplinary or regulatory enforcement actions by any health regulatory board related to such actions or inactions, absent gross negligence or willful misconduct. Any health care provider or person who provides information to any medical review committee, board, group or other entity providing a medical or ethics review pursuant to § 54.1-2990, or makes any finding, opinion, or conclusion as part of such entity shall be immune from civil liability for any act done for, or any utterance or communication made to, such entity unless such act, utterance or communication was the result for gross negligence or willful misconduct. For purposes of this section, health care provider shall have the same meaning as defined in § 8.01-581.1.

Work Group proposed revisions to § 54.1-2990 (10)

B. For purposes of this section, "life-sustaining ~~care~~*treatment*" means any ongoing health care that utilizes mechanical or other artificial means to sustain, restore or supplant a spontaneous vital function~~, including hydration, nutrition, maintenance medication, and cardiopulmonary resuscitation~~.

C. Nothing in this section shall require the provision of health care that the physician is physically or legally unable to provide, or health care that the physician is physically or legally unable to provide without thereby denying the same health care to another patient.

D. Nothing in this article shall be construed to condone, authorize or approve mercy killing or euthanasia, or to permit any affirmative or deliberate act or omission to end life other than to permit the natural process of dying.

Citations

Citations

Abbott, KH, Sago, JG, Breen CM, Abernethy AP, & Tulsky JA. (2001). Families looking back: One year after discussion of withdrawal or withholding of life-sustaining support. *Crit Care Med 29*:197-201

Allen, R, Judkins-Cohn, T, DeValasco, R, Forges, E, Lee, R, Clark, L, & Procunier, M. (2013). Moral distress among healthcare professionals at a health system. *JONA's Healthcare Law, Ethics, and Regulation, 15(3)*: 111-118.

American Medical Association (AMA) Council on Ethical and Judicial Affairs. Medical futility in end-of-life care. *JAMA 281*: 937-941.

Angus et al. (2004). Use of intensive care at the end of life in the United States: An epidemiologic study. *Crit Care Med 32*:638-643.

Azoulay et al. (2009). Prevalence and factors of intensive care unit conflicts: The conflictus study. *Am J Respir Crit Care Med 180*:853-860.

Bosslet et al. (2015). An official ATS/AACN/ACCP/ESICM/SCCM policy statement: responding to requests for potentially inappropriate treatments in intensive care units. *Am J Respir Crit Care Med 191(11)*: 1318-1330.

Breen et al. (2001). Conflict associated with decisions to limit life-sustaining treatment intensive care units. *J Gen Intern Med 16*:283-289.

Citations

Cook DJ, Guyatt GH, Jaeschke R, Reeve J, Spanier A, King D, Molloy DW, Willan A, Streiner DL; Canadian Critical Care Trials Group. (1995). Determinants in Canadian health care workers of the decision to withdraw life support from the critically ill. *JAMA 273*: 703–708.

Fine, RL & Mayo, TW. (2003). Resolution of futility by due process: Early experience with the Texas Advance Directives Act. *Ann Intern Med 138*:743-746.

Hamric AB & Epstein EG. (2017). A health-system-wide moral distress consultation service: Development and evaluation. *HEC Forum 29(2)*: 127-143.

Hamric, A.B. & Blackhall, L.J. (2007). Nurse-physician perspectives on the care of dying patients in intensive care units: Collaboration, moral distress, and ethical climate. *Crit Care Med 35:* 422-529.

Kon et al. (2016). Shared decision making in ICUs: An American College of Critical Care Medicine and American Thoracic Society policy statement. *Crit Care Med 44*:188-201.

McDonagh et al. (2004). Family satisfaction with family conferences about end-of-life care in the intensive care unit: Increased proportion of family speech is associated with increased satisfaction. *Crit Care Med 32*:1484-1488.

Citations

Paris JJ, Billinngs JA, Cummings B, Moreland MP. (2006). Howe v. MGH and Hudson V Texas Children's Hospital: Two approaches to resolving family-physician disputes in end-of-life care. *J Perinatol 26:* 726-729.

Pope, Thaddeus (2013-2014). "Dispute Resolution Mechanisms for Intractable Medical Futility Disputes." *New York Law School Law Review*. 58: 347-368.

Prendergast & Luce (1997). Increasing incidence of withholding and withdrawal of life support from the critically ill. *Am J Respir Crit Care Med 155*:15-20.

Schuster et al. (2014). Investigating conflict in ICUs—is the clinicians' perspective enough? *Crit Care Med 42*:328-335.

Sprung CL, Truog RD, Curtis JR, Joynt GM, Baras M, Michalsen A et al., (2014). Seeking worldwide professional consensus on the principles of end-of-life care for the critically ill. *Am J Respir Crit Care Med 190(8)*: 855-866.

Studdert et al. (2003). Conflict in the care of patients with prolonged stay in the ICU: Types, sources, and predictors. *Intens Care Med 29*:1489-1497.

Swetz et al (2007). "Report of 255 clinical ethics consultations and review of the literature." *Mayo Clinic Proceedings*. 82(6):686-91.

Whitehead, P.B., Herbertson, R.K., Hamric, A.B., Epstein, E.G., & Fisher, J.M. (2015). Moral distress among healthcare professionals: Report of an institution-wide survey. *J Nsg Schol 47(20):* 117-125.