A Proposal to Restore Medical Futility as a Clinical Basis for a DNR Order Under New York Law

By Joseph J. Fins, M.D., M.A.C.P. and Robert N. Swidler, J.D.

Mrs. D, a 91-year-old nursing home resident with dementia, was brought by EMS to the hospital for difficulty breathing. She was diagnosed with bilateral pneumonia, placed on a ventilator, and given antibiotics. After three days her condition deteriorated to multisystem organ failure and sepsis. Her attending physician doubted she would recover, but could not say for sure. But he was certain that if her condition worsened to the point where her heart stopped, resuscitation would be ineffective. Accordingly, he spoke with Ms. D's adult children about a DNR order.

Under New York's former Do-Not-Resuscitate (DNR) Law,[1] which was in effect for 22 years (1988-2010), a physician could write a DNR order for a patient who lacked capacity if he or she determined, among other circumstances, that resuscitation would be "medically futile," another physician concurred, and a surrogate decision-maker consented to the DNR order.[2] If the patient had no surrogate, the physician could write the order based on medical futility without surrogate consent, with the concurrence of another physician.[3]

In 2010, with the enactment of the Family Health Care Decisions Act (FHCDA),[4] the medical futility standard for a DNR orders was superseded by more general criteria for decisions about the withdrawal or withholding of life-sustaining treatment.[5] Overall, the FHCDA has greatly improved care toward the end of life by empowering family decision-makers and establishing clear principles and procedures. But by attempting to create clinical criteria that could apply to all end-of-life decisions, the FHCDA forfeited the helpful specificity of the medical futility standard for DNR decisions, and thereby created problems in clinical practice.

As explained below, end-of-life care would be improved by amending the FHCDA to restore the former "medical futility" standard as one of the alternative criteria for writing a DNR order. These are the views of the authors, but not necessarily those of the organization they are associated with, including the NYS Task Force on Life and the Law.

DNR Orders

A DNR Order is an order written by a physician that directs staff not to attempt to resuscitate a patient in the event the patient has a cardiac arrest—that is, the patient's heartbeat and breathing stops. Resuscitative measures could range from very basic techniques like basic life support (BLS)[6] to advanced technological interventions such as intubation and even the use of more advanced techniques such as ECMO (extracorporeal membrane oxygenation) which is much like a heart-lung bypass machine used during heart surgery.[7] The range of resuscitative options hinge on where the event occurs, and available resources and personnel.

In general, a DNR order is considered when a patient is at high risk of dying, resuscitative efforts would neither alter the outcome nor address underlying disease processes that placed the patient at risk of dying, and such efforts would interfere with a more peaceful death.

New York's Former DNR Law (1988-2010)

New York's former DNR Law, which went into effect in 1988, was based on recommendations by the NYS Task Force on Life and the Law. Governor Mario M. Cuomo and Health Commissioner David Axelrod had asked the Task Force to study DNR orders in the wake of media reports about legally and ethically questionable practices at several hospitals, such as covert DNR orders, slow codes and show codes.[8] The Task Force's position was that a DNR order is ethical and should be lawful if:

(1) the patient has capacity and consents to the order, or

(2) the patient lacks capacity, meets certain clinical criteria, and an appropriate surrogate decision-maker

Joseph J. Fins, M.D., M.A.C.P., is The E. William Davis, Jr. M.D. Professor of Medical Ethics and Chief of the Division of Medical Ethics at Weill Cornell Medical College where he is a Professor of Medicine, Professor of Medical Ethics in Neurology, Professor of Health Care Policy and Research, and Professor of Medicine in Psychiatry. He is the founding Chair of the Ethics Committee of New York-Presbyterian Weill Cornell Medical Center and is an Attending Physician and the Director of Medical Ethics. A member of the Adjunct Faculty of Rockefeller University and Senior Attending Physician at The Rockefeller University Hospital, he co-directs the Consortium for the Advanced Study of Brain Injury at Weill Cornell and Rockefeller. At Yale Law School, he is the Solomon Center Distinguished Scholar in Medicine, Bioethics and the Law. His most recent book is *Rights Come to Mind: Brain Injury, Ethics & The Struggle for Consiousness*. He was appointed by the Governor to the NYS Task Force on Life and the Law in 2006. **Robert N. Swidler** is V.P. Legal Affairs for St. Peter's Health Partners, a not-for-profit health care system in New York's Capital Region composed of hospitals, nursing homes, home care, hospice, a large phyisican practice and other services. Mr. Swidler was Staff Counsel to the NYS Task Force on Life and the Law from 1985-90 and in 2010 was appointed by the Governor as a member of the Task Force. He is also Editor of the *NYSBA Health Law Journal*.

(if there is one) consents to the order based on the patient's wishes if reasonably known, or else best interests.[9]

The resulting DNR Law reflected those principles. With respect to the clinical criteria, under the DNR law a surrogate decision-maker could consent to the entry of a DNR order for a patient who lacked capacity if physicians found that the patient met any one of the following four clinical criteria:

- the patient has a terminal condition;
- the patient is permanently unconscious;
- resuscitation would be medically futile; or
- resuscitation would impose an extraordinary burden on the patient in light of the patient`s medical condition and the expected outcome of resuscitation for the patient.[10]

Moreover, for a patient who did not have a surrogate, a DNR order could be entered if two physicians found to a reasonable degree of medical certainty that "resuscitation would be medically futile."[11]

The statute defined "medically futile" to mean

> that cardiopulmonary resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs.[12]

This provision was intended to limit this discretionary authority to examples of what has been described in the medical ethics literature as "physiological futility,"[13] in which it is not possible to either provide treatment or that treatment to a reasonable degree of medical certainty would not be successful. An example of the former might be a mass in the trachea that precludes the ability to place a breathing tube necessary for ventilation. An alternate scenario might be a refractory chemical abnormality called acidosis which makes it difficult to treat malignant cardiac arrhythmias.[14] Under these circumstances continued resuscitative efforts would be futile. Indeed, the principle of futility is invoked at the *end* of every failed cardiac resuscitation when the attending physician decides to stop her efforts to revive the patient. At that juncture she knows retrospectively that her efforts have been, and will continue to be, futile.[15]

The DNR Law was controversial for a range of reasons.[16] But there do not appear to have been concerns about the statutory definition of medical futility or the ability to recognize medical futility in clinical practice.[17] Indeed, for over two decades it was part of New York's clinical landscape and a useful means to provide competent and compassionate care at life's end. As such, we urge its reincorporation into New York law.

The Family Health Care Decisions Act (2010)

The former DNR Law addressed only one specific end-of-life decision: the withholding of cardio-pulmonary resuscitation. There remained a compelling need to authorize surrogate decisions for the withdrawal or withholding of other life-sustaining treatments such as a ventilator, feeding tube, dialysis, and life-sustaining medications or surgeries. As important, there was a need to override New York's stringent "clear and convincing evidence" rule for such decisions,[18] which restricted family decision-making at the end of life.

In 1992, the Task Force authored a report "When Others Must Choose" recommending a more general surrogate decision-making law that closely followed the DNR Law framework.[19] It advised that surrogate consent to the withdrawal or withholding of life-sustaining treatment from a patient who lacks capacity is ethical and should be lawful if the patient meets certain clinical criteria, and an appropriate surrogate decision-maker (if there is one) consents to the order based on the patient's wishes if reasonably known. If they were not known, a decision could be based upon a best interests.

In 2010, 18 years after the Task Force issued its report, the New York State Legislature passed the Family Health Care Decisions Act (FHCDA).[20] The statute is closely based on the Task Force recommendations.[21]

Surrogate Consent to a DNR Order Under the FHCDA

The passage of the FHCDA repealed New York's former DNR Law with respect to DNR orders in hospitals and nursing homes, and made such decisions subject to FHCDA's more general standards for the withholding and withdrawing of life-sustaining treatment.[22] The rationale was that there was no longer a need for a separate surrogate decision-making law for DNR decisions; that DNR decisions could be subject to the same clinical criteria that apply to other surrogate decisions to forgo life-sustaining treatment. The FHCDA criteria for surrogate consent to a DNR order are as follows:[23]

> (i) Treatment would be an extraordinary burden to the patient and an attending physician determines, with the independent concurrence of another physician, that, to a reasonable degree of medical certainty and in accord with accepted medical standards,
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> (A) the patient has an illness or injury which can be expected to cause death within six months, whether or not treatment is provided; or
>
> (B) the patient is permanently unconscious;[24] or

(ii) The provision of treatment would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or extraordinarily burdensome under the circumstances and the patient has an irreversible or incurable condition, as determined by an attending physician with the independent concurrence of another physician to a reasonable degree of medical certainty and in accord with accepted medical standards.

Notably, the FHCDA criteria does not explicitly list medical futility as a basis for a DNR order.[25] Arguably every case that would have met the former DNR Law's medical futility standard will meet the current FHCDA "inhumane or extraordinarily burdensome" standard. But that standard is more about a proportionality versus a futility assessment. Under the FHCDA the calculus is the relationship of burdens to benefits in which decisions to forgo life-sustaining therapy can be made when ongoing treatment is so disproportionate as to constitute a burden. But in practice, the standard is problematic for clinicians to apply. The determination that resuscitation would be "inhumane and extraordinarily burdensome" under the circumstances involves more of a qualitative, subjective, value judgment than the more quantitative, objective, medical prognosis that CPR "will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs."

Consider the case described at the outset of this article. Under the former DNR Law, the attending physician and a concurring physician could confidently state that if Ms. D's condition declined to the point where her heart stopped, resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs. Indeed this case is a classic and common situation in which a DNR order would be advisable and appropriate.

The FHCDA criteria is more difficult to apply to this case. An attending and concurring physician could feel less confident about stating—indeed less qualified to state—that CPR "would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or extraordinarily burdensome under the circumstances," especially because patients become unconscious when resuscitation is performed. The burden is often more for those who witness or participate in the resuscitative efforts.

Moreover, the physicians might be hesitant to declare that "the patient has an irreversible or incurable condition." It is true that her dementia cannot be treated and is progressive and terminal, but her cardiac arrest could be a function of her pneumonia which might be reversible. Despite these interpretive issues raised by the provisions of the FHCDA, the ethical and clinical appropriateness of a DNR order in this case is as strong now as it was when the former DNR Law was in effect.

To be sure, many—perhaps most—physicians will conclude that the case described meets the "inhumane or extraordinarily burdensome" test and the "irreversible or incurable condition" test. Moreover in many cases, the DNR order can be supported by a finding that the patient is "expected to die within six months."

Even so, the removal of the DNR medical futility standard has diminished the clarity of the clinical standard and created a likelihood of greater variability in physician determinations of DNR eligibility in clinically similar cases.

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Put differently, the FHCDA, by attempting to create clinical criteria that could apply to all end-of-life decisions, forfeited the helpful specificity of the prior medical futility standard for DNR decisions.

The futility standard had important merit beyond just clarity: it had the effect of reducing the emotional burden on the conflicted surrogate who felt that they could not let go. Once a physician notifies the surrogate that resuscitation would be medically futile, the difficulty of this decision is lessened. The surrogate is apt to feel that their consent to the DNR order is not so much their personal choice as much as a recognition of the medical circumstances and the futility of attempting resuscitation. Reinserting the futility provision would allow a clinician to suggest that resuscitation not be attempted because she views its provision as futile, and seek a surrogate's acknowledgment rather than having to pose the choice as more neutral question. In our view, by providing this guidance to surrogates about what is in the realm of the medically possible, clinicians can better lead families through the challenges of decisions at life's end.

DNR Orders for Patients Without Surrogates

A similar, and perhaps greater, problem relates to decisions for patients who do not have a surrogate. Under the former DNR Law, when a patient lacked capacity and did not have a surrogate, a DNR order could be entered only if

the physician and a concurring physician determined that resuscitation would be medically futile.[26] Here again, the FHCDA eliminated that DNR-specific standard in favor of a more general standard for the withdrawal or withholding of any life-sustaining treatment. The standard is very restrictive: treatment can be withheld (and therefore a DNR order can be issued) if the attending physician and another physician determine to a reasonable degree of medical certainty that:

(i) life-sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and

(ii) the provision of life-sustaining treatment would violate accepted medical standards...[27]

The imminently dying standard resembles the "medical futility" standard, but is problematic as applied to the DNR decision. When a DNR order was based on medical futility, the physicians were saying "*if and when in the future this patient's heart stops*, it will not be possible to start it again, or start it for very long." But the medical futility standard did not ask the physicians to predict when that cardiac arrest could occur; indeed, it might not occur for a very long time and prognostication at the end of life can be very difficult.[28]

In contrast, some physician might read the FHCDA standard as requiring physicians to determine that the patient is *imminently dying at the time they are writing the DNR order*. If so, that would be far more restrictive than the former DNR Law's medical futility standard was and limit decisions to withhold or withdraw care to patients clearly in extremis. That reading would exclude patients who if they were to have a cardiac arrest would not likely have a successful resuscitation.

To be sure, the FHCDA standard does not have to be read that narrowly. It should be read to mean, as applied to a DNR decision, that doctors must find that the patient will die imminently *if and when the patient has a cardiac arrest*—which is the moment that the treatment will be withheld. A Q&A on the New York State Bar Association's FHCDA Information Center takes this position.[29]

But the fact is, the clause is ambiguous, and capable of two interpretations. Some clinicians tend to read it in a conservative manner, perhaps making the reach of the law more narrow than what was envisioned by legislative intent. It therefore creates a risk of variability in physician determinations in clinically similar cases. Restoring the medical futility standard would enhance consistency, and reduce concern about an excessively narrow application of the "imminent dying" test.

If we reconsider the case of Ms. D., but now assume she has no close family or friends, the challenge of this provision becomes clear. Under the former DNR Law the attending with a concurring physician could have a written a DNR order based on the finding that CPR would not work. Under the FHCDA standard, the attending would struggle over two more complicated questions: (i) whether the patient will die imminently (and whether that refers to at the time the order is written or at the time of a future cardiac arrest); and (ii) whether CPR would violate accepted medical standards. Here again, these more general standards would likely result in variability in determinations in like clinical cases—with no rationale for the variability other than difficulties applying the standard.

Legislative Proposal

The problems noted above can easily be remedied as a drafting matter: The FHCDA should be amended to restore medical futility as one of the bases for writing a DNR order when either a surrogate consents to the DNR order or when a patient does not have a surrogate. This can be done while leaving in place the existing criteria as other bases to write a DNR order.

Legislative bills have been introduced in the Legislature since 2011 that would accomplish such amendment.[30] Unfortunately a bill has not yet passed in either the state Assembly or Senate. We urge that this be done.

Legislators are understandably wary about any bill that addresses the topics of DNR and medical futility. But in this instance, they can be reassured: the bill does not introduce a new untested standard; it simply restores the standard that was in effect and worked well for 23 years. And the bill does not authorize a physician to write a futility DNR order unilaterally when there is a surrogate; if there is a surrogate, that surrogate's consent is required for the DNR order.

Instead, the bill will help improve end-of-life decisions by clarifying that a physician can write a DNR order for a patient who lacks capacity, among other circumstances, when the attending physician finds that resuscitation would be "medically futile," another physician concurs, and a surrogate decision-maker consents to the DNR order. And if the patient has no surrogate, an attending physician, with the concurrence of another physician, could write the order based on medical futility in the absence of a surrogate.

Other Issues

A bill to restore the medical futility will not resolve all the issues relating to the entry of DNR orders, some of which are long-standing and some recent. For example:

Do Not Resuscitate vs. Do Not Intubate. The confusion between DNR and DNI persists. It is our view that an order not to intubate must always be accompanied by a DNR order, as intubation is a key component of resuscitation. Conversely, patients can be intubated and still be DNR, when intubation is elective and not in the setting of a cardiac arrest.

Diagnosing Permanent Unconsciousness. Recent data suggests that upwards of 41% of patients thought to be permanently unconscious in the permanent vegetative

state are in fact in the minimally conscious state (MCS). We urge the Department of Health to issue clinical guidelines to assess and diagnose disorders of consciousness, much as it did for the determination of brain death.[31]

DNR Suspension During Surgery. We would like to see DOH guidance or regulations, such as those that existed when the former DNR Law was in place, stating that DNR orders cannot be unilaterally suspended during surgery without the patient's or surrogate's consent and that the reversal of DNR status could not be a precondition for surgery, which is often palliative under these circumstances.[32] This is the "required reconsideration" standard adopted by the American College of Surgeons.[33]

New Resuscitative Technologies. Reinstating provisions of the former DNR Law would not address its appropriateness and applicability to new resuscitative technologies. We think some of these issues are ripe for review by the Task Force with input from professionals and the public.

But the perfect should not be the enemy of the good. There is much to be done to update our laws about end-of-life care in New York. But short of those more ambitious goals, the Legislature can act promptly to make what should be a noncontroversial, simple improvement to the FHCDA: restore the former medical futility standard as one of the bases for a DNR Order.

Endnotes

1. NY Public Health Law (PHL) Article 29-B, added by NY Laws of 1987, chapter 818, eff. April 1 1988. *See also* the Department of Health's nearly identical hospital regulations. 10 NYCRR § 405.43 (repealed March 11, 2014).
2. PHL § 2965.3(c).
3. Id., § 2966.1
4. PHL Article 29-CC, added by NY Laws of 2010, chapter 8.
5. PHL § 2994-d.5.
6. E.g., manual chest compression with the mouth-to-mouth supply of oxygen.
7. This is not a description of the standard of care, but a description of the range of technological interventions that might be used in a resuscitation effort.
8. See *Law Proposed for Withholding Emergency Care*, NY Times, April 20, 1986, p. 38.
9. NYS Task Force on Life and the Law, *Do-Not-Resuscitate Orders* (1986).
10. Former DNR Law § 2965.3(c).
11. PHL § 2966.1(a).
12. PHL § 2961.12.
13. See S.J. Youngner, M.D., *Who Defines Futility?*, J. American Medical Assn Oct. 14, 1988 2094-5.
14. See NYS Task Force on Life and the Law, When Others Must Choose (March 1992) p. 196.
15. J.J. Fins, *A Palliative Ethic of Care: Clinical Wisdom at Life's End* (Sudbury MA: Jones and Bartlett Publishers, 2006).
16. See e.g., R. Baker and M. Strosberg, *Legislating Medical Ethics: A Study of the NY Do-Not-Resuscitate Law* (Springer 1995).
17. However, there was considerable debate about the need for surrogate consent in instances where physicians determined that resuscitation would be medically futile. That is not the topic of this article. See Youngner, note 12 above.
18. See R. Swidler, *Harsh State Rule on End of Life Care Remains in Need of Reform,* N.Y.L.J., Jan 26, 2000, p. 1.
19. NYS Task Force on Life and the Law, *When Others Must Choose* (1992).
20. Ch. 8, L. 2010.
21. See R. Swidler, *The Family Health Care Decisions Act: The Legal and Political Background, Key Provisions and Emerging Issues*, N.Y. St. B.J. (June 2010), p. 18.
22. To be precise, Ch. 8, L. 2010 amended the former DNR Law, PHL Article 29-B, to make it applicable only in psychiatric hospitals, psychiatric units, and developmental centers—locations that the FHCDA did not reach.
23. PHL § 2994.d.5. The criteria for a patient without a surrogate are different, and are discussed further below.
24. We discuss this standard in the final section of this article.
25. NY Public Health Law § 2994-d.5.
26. NY Public Health Law § 2966.1.
27. NY Public Health Law § 2994-g.5.
28. See Nicholas A. Christakis, *Death Foretold: Prophecy and Prognosis in Medical Care* (U. Chicago 1999).
29. See http://www.nysba.org/ FAQ VI.1:

    > VI. Health care decisions for adult patients without surrogates. (PHL §2994-g) (Revised Sept. 21, 2010).
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    > 1. Q—Under the former DNR law, a DNR order could be entered for an incapable patient who did not have a surrogate if the physician and a concurring physician determined that resuscitation would be" medically futile" (i.e., if CPR would "be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs"). Can a physician still do that?
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    > A—The language of the standard has changed, but it still ordinarily supports the entry of a DNR order if resuscitation would be "medically futile" as defined above. Under the FHCDA, the physician and a concurring physician would need to determine that (i) attempted resuscitation (in the event of arrest) would offer the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and (ii) the attempt would violate accepted medical standards.
30. E.g., A.3991 (Gottfried)(2017); S.4796 (Hannon)/A.6966 (Gottfried) (2015).
31. See Schnakers C, Vanhaudenhuyse A, Giacino J, Ventura M, Boly M, Majerus S, Moonen G, Laureys S., *Diagnostic Accuracy of the Vegetative and Minimally Conscious State: Clinical Consensus Versus Standardized Neurobehavioral Assessment*, BMC Neurology, 2009, 9:35. More generally see Fins JJ., Rights Come to Mind: Brain Injury, Ethics and the Struggle for Consciousness (New York: Cambridge University Press, 2015).
32. See *NYS DOH Health Facilities Memo* H-27; Rhcf-22; Hha-19; Hospice-10, Subject: DNR Law Changes (11/2/1992) at p. 14-5.
33. See www.facs.org/about-acs/statements/19-advance-directives.