Point/Counterpoint Editorial

Informed Consent Should Be Obtained for Apnea Testing in the Determination of Death by Neurological Criteria

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Point/Counterpoint editorials present a debate by content experts with different interpretations of the evidence supporting an approach to a topic. The authors on each side of the debate develop a rationale for their stance and then are given an opportunity to view and respond to the rationale provided counter to their stance.

This is the Counterpoint and Rebuttal to a forthcoming Point/Counterpoint Editorial between Professor Thaddeus Pope and Dr. Alan Shewmon.

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Counterpoint: Informed Consent Should Be Obtained for Apnea Testing in the Determination of Death by Neurological Criteria. No.

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For four decades, in almost every U.S. jurisdiction, the determination of death has been governed by the Uniform Determination of Death Act (UDDA).[1] But since 2015, this law has come under increasing scrutiny in legislatures, courts, and scholarly literature.[2] Most significantly, in July 2021, the Uniform Law Commission appointed a Drafting Committee to revise the UDDA. One of four charter questions for this Committee is whether to amend the UDDA to better clarify whether clinicians must obtain consent before testing for death by neurological criteria, commonly referred to as "brain death" (BD/DNC).

The axiomatic general rules for medical consent are widely understood. Clinicians must normally obtain patient or surrogate consent before administering any test or procedure. Otherwise, the clinician commits not just malpractice but tortious battery. This fundamental principle of medical ethics has been firmly established for more than 100 years.[3] But this general consent rule carves out several specific exceptions. The most salient is the emergency exception which permits clinicians to act unilaterally and take medically indicated measures without consent when: (1) the patient's health is in jeopardy, (2) they need immediate medical attention, and (3) no person authorized to consent is available.

BD/DNC testing is another exception to the general consent requirement. For three reasons, it should remain an exception. First, settled law holds that clinicians do not need consent to perform BD/DNC testing. Second, there are compelling policy reasons to maintain this position. Third, the absence of a consent requirement does not foreclose offering reasonable accommodations.

U.S. Law Does Not Require Consent for BD/DNC Testing

The question of consent for BD/DNC testing is not new. It has been repeatedly asked and answered by both legislatures and courts.[2] The overwhelmingly consistent response is that consent is not required. This is confirmed by the UDDA itself, by other statutes and regulations, and by a growing number of court decisions.

The UDDA provides that "an individual who has sustained . . . irreversible cessation of all functions of the entire brain, including the brainstem, is dead."[1] But the UDDA was deliberately silent on exactly how clinicians should measure irreversible cessation. Instead, the

UDDA provides that "determination of death must be made in accordance with accepted medical standards."[1] Drafters deliberately designed the UDDA to provide only a general standard, delegating and deferring to the medical profession responsibility for establishing the precise method and manner for assessing satisfaction of the legal standard.[4] As in many other areas of health law, legal duties under the UDDA piggyback on, and are shaped by, the medical standard of care set by clinicians.

Specifically, the UDDA requires that clinicians make determinations of death in accordance with "accepted medical standards."[1] Because those standards themselves do not require consent, neither does the UDDA require consent. Evidence on this point is significant and compelling. Among other substantiation, we can look both (1) to professional organization position statements and (2) to custom and practice.

Every relevant professional society maintains that consent is not required. For example, the American Academy of Neurology states that "its members have both the moral authority and professional responsibility . . . to perform a brain death evaluation including apnea testing . . . without obligation to obtain informed consent."[5] The World Brain Death Project was joined thirty-three medical societies and five world federations in holding that consent is not needed prior to assessment for brain death.[6]

Furthermore, looking to professional society position statements is not the only way to ascertain "accepted medical standards." We can also look to custom and practice. Surveys of individual clinicians accord with professional society policies. Surveys show that 78% of neurologists and 72% of pediatric neurologists strongly or somewhat disagreed that physicians should obtain consent from a patient's family before performing a brain death evaluation.[7,8]

Unlike the UDDA itself, some statutes and regulations more directly and explicitly address consent for BD/DNC testing.[2] Every single one provides that consent is not required. Moreover, some laws go even further, requiring timely BD/DNC testing by mandating that individuals are "declared dead within an acceptable time frame."[9] Similarly revealing are statutes that require "reasonable accommodation" for families when they assert a religious or moral objection to BD/DNC.[2] But despite their enfolding objective, these laws address only organ sustaining treatment ***after*** determination of BD/DNC. None requires consent to, or delay of, BD/DNC testing.[2]

Finally, the UDDA and other statutes and regulations are not the only authorities holding that consent is not required for BD/DNC testing. Over the past few years, the consent question has repeatedly reached the courts (Table 1).[2] While it might appear, on cursory examination, that the courts are evenly split; a closer look shows more consistency. Every judgment that

was carefully briefed and argued holds that consent is not required. Those requiring consent were issued under exigent circumstances when the family sought a temporary restraining order.

Table 1				
Court Case	**State**	**Year**	**Posture**	**Consent**
Sharon Lucy Frederick	New York	2020	Merits	No
Mirranda Lawson	Virginia	2016	Merits	No
Motl Brody	Washington, DC	2008	Merits	No
Tara Hawkins	Georgia	2007	Merits	No
Nick Torres	Texas	2020	TRO	No
Allen Callaway	Montana	2016	TRO	Yes
Alex Pierce	California	2016	TRO	Yes
Brett Shively	Kansas	2006	TRO	Yes

U.S. Law Should Not Require Consent for BD/DNC Testing

This sizable and stable legal and ethical consensus weighs heavily toward not requiring consent. Opponents bear the burden of presenting compelling reasons why the status quo is inadequate and should be replaced. Not only are these justifications absent but also there are compelling policy reasons not to require consent.

Determining whether a patient is alive, or dead, is the most fundamental aspect of providing medical care.[10] First, clinicians must confirm that the individual is eligible for healthcare services. Otherwise, they commit fraud by billing for services that are not "medically necessary." Second, clinicians must be good stewards of scarce resources like ICU beds. A consent requirement would permit families to indefinitely prevent the determination, and therefore, the declaration of death. As commentators in a previous pro/con debate observed, hospitals are "not places to maintain the dead."[11]

Clinicians May Still Offer Reasonable Accommodation

Proponents of a consent requirement for BD/DNC testing argue that it would be compassionate and respectful. But these same benefits can be achieved without mandating consent. Clinicians in most states already regularly offer accommodations of 24 to 72 hours even though this is legally required only in California, Illinois, and New York.[2] Most discussion of accommodation focuses on time after determination and declaration, so families have an opportunity to gather and say goodbye. But clinicians can also (and already do) offer

accommodations before determination.[12] They can delay testing to permit the family both to process the situation and to explore transfer options.

Conclusion

While clinicians must normally obtain informed consent before administering tests and procedures, BD/DNC testing is a well-established exception to this requirement. Robust policy reasons compel maintaining this settled convention.

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Rebuttal: Informed Consent Should Be Obtained for Apnea Testing in the Determination of Death by Neurological Criteria. No.

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Shewmon completely avoids addressing the question of whether informed consent should be obtained for apnea testing in the determination of death by neurological criteria. For Shewmon, this question is moot and "almost absurd" because he argues that we should never use apnea testing. He contends that it is unreliable, unsafe, and completely replaceable with ancillary testing. The question of consent arises only for those tests we plan to administer. Since Shewmon contends that apnea testing should never be administered, he further contends that the question of consent never arises.

But Shewmon's clamor to abandon apnea testing seems quixotic given its repeatedly reconfirmed central role in the determination of death by neurological criteria. Apnea testing is the final confirmatory test in both adult and pediatric guidelines in the United States.[1-2] More broadly, apnea testing is required by the World Brain Death Project, a consensus document endorsed by almost 30 of the most important medical societies in intensive care, neurology, and neurosurgery.[3] Proposed revisions to the Uniform Determination of Death Act are calculated to reduce persistent non-uniformity in apnea testing (Table 1).[4-5] Yet even this variability does not include the complete exclusion of apnea testing.[6]

Rather than engage Shewmon on the purely clinical and scientific issue of the need and value of apnea testing, I remain focused on the original ethical and legal question of consent. Why? Because even if we followed Shewmon and invariably used ancillary testing instead of apnea testing, the consent question would remain.

For ancillary testing, the World Brain Death Project recommends blood flow-based methods such as digital subtraction angiography and radionuclide studies.[3] Must informed consent be obtained for this testing? This question is just as relevant and pressing as the question of consent for apnea testing because many families object to ancillary testing for the same reason that they object to apnea testing. They do not want clinicians to determine or declare death. Sometimes they want additional time to explore options or to reach acceptance. Other times, they object for religious reasons to obtain indefinite ICU support. Whatever their reason, the objective is clear. By preventing the required testing, these objectors aim to forestall determination of death by neurological criteria.

But this strategy erroneously assumes that clinicians must obtain consent for ancillary testing in the first place. In fact, consent is not required. This rule might seem counterintuitive and surprising. Since angiography and radionuclide studies involve the injection of either contrast material or isotopes into the patient, they seem to fall within the scope of standard requirements for consent.[7] But testing for death by neurological criteria (by any method) is a well-established exception to the consent requirement. Settled law holds that clinicians do not need consent to perform brain death testing (Table 1), and there are compelling policy reasons to maintain this position.

Table 1

	Consent Required	Delay Permitted	Uniformity Needed
Apnea Testing	No	Yes	Yes
Ancillary Testing	No	Yes	Yes

In short, since clinicians do not need consent for apnea testing, they do not need consent for less risky ancillary testing. Individual institutions may continue to offer reasonable accommodations by temporarily delaying testing. But that is not a legal requirement, nor should it become one.

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