

Legal Update 2016
Top 10 Legal Developments
in Bioethics

ASBH Annual Meeting
Washington, DC • October 8, 2015

Thaddeus Mason Pope, JD, PhD
Mitchell Hamline Health Law Institute

15 min

3

Brain Death
Futility
PDA

Brain
Death

Total
brain = death
failure



Legally
settled
since 1980s

3 attacks
on brain death

Attack 1 of 3

Accommodation after death

Not questioning brain death criteria

Not questioning application to this patient

But want **continued** organ support

Annals of Internal Medicine

American College of Physicians Ethics Manual
Sixth Edition

Lois Snyder, JD, for the American College of Physicians Ethics, Professionalism, and Human Rights Committee*

“After a patient . . . brain dead . . . medical support should be **discontinued**.”

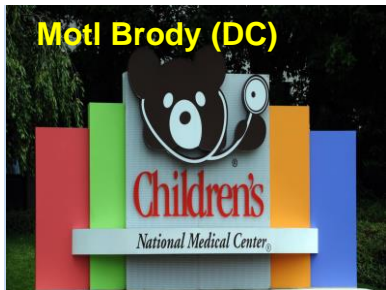


“reasonably brief period”

24 - 48 hours



Indefinite accommodation (until CP death)





Uniformly denied

Attack
2 of 3

Consent
for apnea
test

Final confirmatory test before declaring death

Remove ventilator
No drive to breathe → dead

No right to treatment **after** death
Other than brief accommodation

Prevent from
being declared
death



Refuse
consent to
apnea test

No apnea test

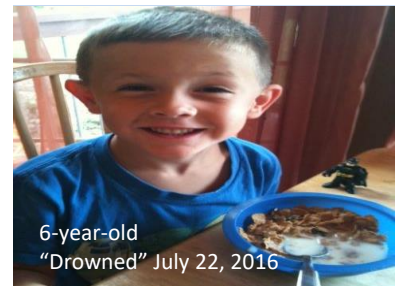


No determination
of death

Do clinicians
need **consent**
for apnea test?

Yes

**Allen
Callaway**



6-year-old
"Drowned" July 22, 2016



Tasha Dawn Stone

FILED
SEP 23 2016
Shaw Adams
CLERK OF DISTRICT COURT
MONTANA COUNTY

MONTANA NINTH JUDICIAL DISTRICT COURT, PONDERA COUNTY

IN THE MATTER OF THE
GUARDIANSHIP OF A.C.,

a minor.

Case No. DG-16-08

FINDINGS OF FACT,
CONCLUSIONS OF LAW AND
ORDER

I. SVH's request for a judicial declaration permitting SVH to conduct testing on A.C. to determine his brain activity over the guardian's objections is denied.

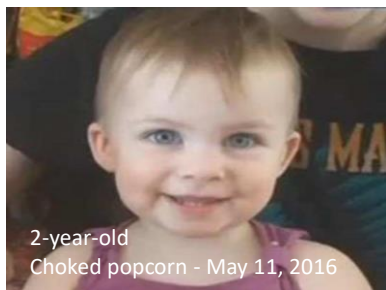
II. A.C.'s guardian and mother has the sole authority to make medical decisions on A.C.'s behalf, including the decision as to whether any future brain functionality examinations should be administered.

Consent
not
required

Mirranda
Lawson



Richmond, Virginia



2-year-old
Choked popcorn - May 11, 2016

I Alison Lawson and Patrick Lawson
refuse any sort of "Brain Dead" testing including
the "Apnea" test on our daughter Mirranda
Grace Lawson. We do not want the ventilator
removed or cut-off for any amount of time.
We are Christians and it is against our
religious beliefs to remove the vent-lator.
Her heart is still beating. Removing life support
will cause death. That is murder and is
against the Christian faith.

Signed Alison Lawson Patrick Lawson
5/20/16 5/20/16

Witnessed Kathy Ray Silvia
Witnessed Sam Bards Stacy

June 10, 2016

The respondent is hereby allowed to administer the apnea test on the subject infant child, who is two years of age, under such mitigating and supportive measures as may be medically necessary and required for the purpose of a determination of the existence, extent, and viability of brain stem activity and thereafter to make or recommend any treatment or in the alternative, make a determination of death as provided by law pursuant to Va. Code § 54.1-2972.

IN THE
SUPREME COURT OF VIRGINIA
Record No. 161321
PATRICK B. LAWSON and
ALISON J. LAWSON,
Appellants,
v.
VCU MEDICAL CENTER, d/b/a
CHILDREN'S HOSPITAL OF RICHMOND
AT VCU, and d/b/a VCU HEALTH SYSTEM
Appellee.
IN RE: MIRRANDA GRACE LAWSON
Appeal From The
Richmond Circuit Court – Case No.: CL16-2358
VCU HEALTH SYSTEM AUTHORITY'S
BRIEF IN OPPOSITION



Dead → No
duty
treat

~~Dead~~ → No
duty
treat

US ICUs will have
more (probably)
dead kids

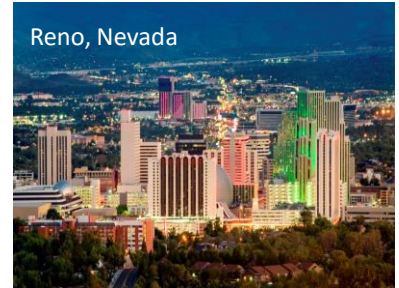
Often full
Others **denied**
opportunity of
ICU benefit

Attack
3 of 3

Are the medical
criteria for
DDNC **legally**
sufficient

AAN does not measure what the **UDDA** requires

Aden Hailu



Aden Hailu



April 1, 2015

Catastrophic anoxic brain injury during exploratory laparotomy

May 28, 2015

Met AAN criteria for brain death



Trial court

AAN criteria met
Aden **is** dead



Irrelevant if Aden meets AAN criteria
They are **not** the "right" criteria

DDNC requires "irreversible cessation . . . **all** functions of the . . . **entire** brain"

Nev. Rev. Stat. 451.007(1)

Trial court did **not consider** whether AAN measures

"irreversible cessation . . . **all** functions of the . . . **entire** brain"

DDNC "must be made in accordance with **accepted medical standards.**"

Nev. Rev. Stat. 451.007(2)

Trial court did **not consider** whether AAN are

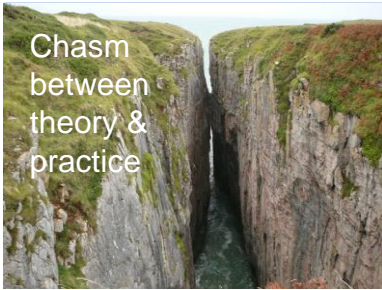
"accepted medical standards"



May need to **amend**
Legal criteria
Medical criteria
Both

PDA





Evidence based educational tools



Accurate
Complete
Understandable

> 130
RCTs



BUT

Very little clinical usage

“Promise remains elusive”



Move PDAs from lab to clinic

No PDA



Assure PDA quality

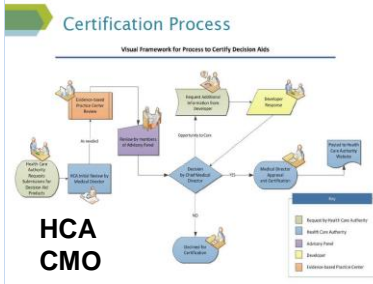
Certification



Criteria

Final Set of Certification Criteria	
<p>Does the patient decision aid adequately:</p> <ol style="list-style-type: none"> 1. Describe the health condition or problem 2. Explicitly state the decision under consideration 3. Identify the eligible or target audience 4. Describe the options available for the decision, including non-treatment 5. Describe the positive features of each option (benefits) 6. Describe the negative features of each option (harms, side effects, disadvantages) 7. Help patients clarify their values for outcomes of options by asking patients to consider or rate which positive and negative features matter most to them AND/OR (b) describing each option to help patients imagine the physical, social (e.g. impact on personal, family, or work life) and/or psychological effects 8. Make it possible to compare features of available options 9. Show positive and negative features of options with balanced detail 10. Provide information about the funding sources for development 11. Report whether authors or their affiliates stand to gain or lose by choosing patients made using the PDA 12. Include authors'/developers' credentials or qualifications 13. Provide date of most recent revision (or production) 	<p>Additional Criteria for Screening and/Testing, if applicable:</p> <ol style="list-style-type: none"> 14. Describe what the test is designed to measure 15. Describe the next steps taken if test detects a condition/problem 16. Describe the next steps if no condition/problem detected 17. Describe the consequences of detection that would not have caused problems if the screen was not done 18. Include information about chances of false negative result 19. Include information about chances of false positive result 20. Include information about chances of false negative result 21. Include information about chances of false positive result <p>Does the Patient Decision Aid and/or the accompanying external documentation (including responses to the application for certification) adequately:</p> <ul style="list-style-type: none"> • Disclose and describe actual or potential financial or professional conflicts of interest? • Fully describe the efforts used to eliminate bias in the decision aid content and presentation? • Demonstrate developer entities and personnel are free from listed disqualifications in Attachment A? • Demonstrate that the Patient Decision Aid has been developed and updated (if applicable) using high quality evidence in a systematic and unbiased fashion? • Demonstrate that the developer tested its decision aid with patients and incorporated these learnings into its tool?

Process



In use

Labor & Delivery
Especially C-section vaginal delivery

Next priority areas:
Joint replacement and spine care (2017)
Cardiac care and end of life care (2018)



Contract with an entity to “synthesize evidence” and establish “consensus based standards”



www.qualityforum.org/Decision_Aids.aspx
tinyurl.com/NQFPDA

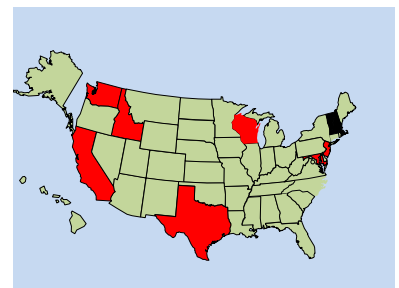
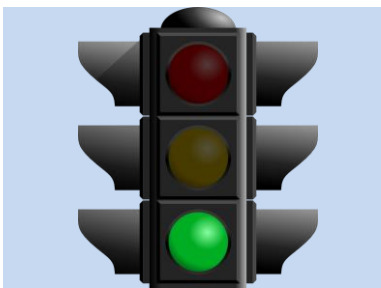
Please comment
by October 14

Project meetings:

- June 22-23, 2016 In-Person Meeting
 - » Review pre-meeting draft materials:
 - » Environmental scan
 - » Business model
 - » White paper
- August Post In-Person Meeting Webinar

Final Report:

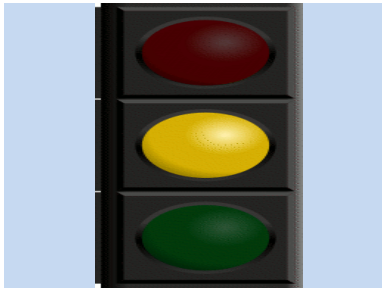
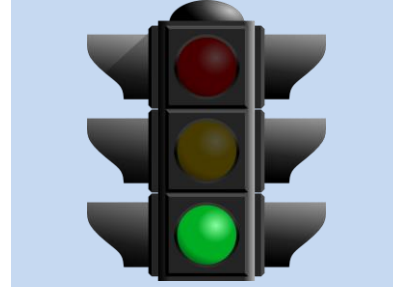
- December 2016



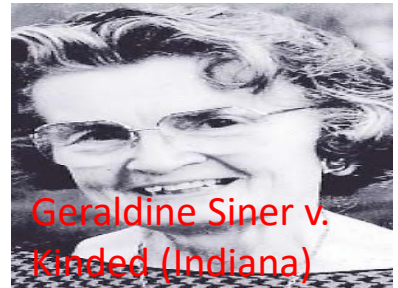


Chris Dunn
v.
Methodist
Hospital

Trial:
Jan. 2017



More lawsuits
for damages



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